HemoCue®
B-Hemoglobin Data Management Analyzer

Operating Manual

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This Operating Manual contains instructions for set-up, quality control testing, patient testing, and troubleshooting of the HemoCue® B-Hemoglobin Data Management Analyzer. This manual is intended for use by health care professionals trained in measuring blood hemoglobin.

The HemoCue B-Hemoglobin Data Management Analyzer (hereafter referred to as "Analyzer") is a compact, portable, yet versatile, blood hemoglobin measurement system. It is ideally suited for health care facilities that require central lab quality values in less than a minute, with exceptional accuracy and precision.

System features include:

- **Powerful data management support for decentralized testing**: Stores results for up to 1,000 records, including Patient ID, Operator ID, instrument serial number, date, time, and Quality Control (QC) results. Records can be reviewed directly on the Analyzer's display window.

- **Highly Customizable**: More than thirty user-definable parameters can be customized to tailor hemoglobin testing to individual facility QC/QA programs.

- **Communication Features enable permanent medical recording**: Can be connected to, and controlled from, a personal computer (PC). Analyzer information can then be transferred to the PC for a permanent medical record.

- **Report Flexibility and Data Storage**: The Analyzer can store and download to a PC all test results necessary for analysis of data and generation of reports required by accrediting regulatory organizations. The "Review and List" function can be used to review all data currently stored in the Analyzer. ***Note:*** *HemoCue's related software programs provide the capability of generating various reports, including patient results, quality control results, and many other specialized reports.*

- **Control of Linearity and Proficiency testing**: Can be used to record linearity and proficiency testing.

- **Extensive Quality Control functions**: Provides patient test lockout when user pre-set conditions are not fulfilled. Offers patient and QC test lockouts if disposable reagents or QC products have expired their shelf-life.

- **Display**: High contrast LCD display which helps guide the operator through each step.

- **Power**: Can be powered either by batteries or the HemoCue AC Adapter.

- **Serial Outputs**: Two RS-232 compatible serial output ports are standard.

1.1 Intended Use

Quantitative determination of hemoglobin in whole blood using a specially designed photometer and specially designed microcuvettes, HemoCue B-Hemoglobin Microcuvettes.

HemoCue B-Hemoglobin Microcuvettes do not fit the HemoCue B-Glucose photometer and are only appropriate with the HemoCue B-Hemoglobin photometer.

1.2 System Components and Description

The system is comprised of the Analyzer and disposable HemoCue B-Hemoglobin Microcuvettes. Although cuvettes made by other manufacturers may fit the cuvette holder, *only* HemoCue B-Hemoglobin Microcuvettes should be used. HemoCue can not guarantee the results if other cuvettes are being used.

The polystyrene plastic microcuvettes are pre-filled with reagents in dry form. Each microcuvette is used for measuring the sample, as both a reaction vessel and a measuring cuvette. No dilution is required.

***Figure 1A**: Placing a filled microcuvette into the Analyzer*

The microcuvette cavity contains the reagents deposited on its inner walls. The 10 µl blood sample is drawn into the cavity by capillary action and is spontaneously mixed with the reagents. Measurement of blood hemoglobin takes place in the Analyzer, in which the absorbance is measured and the hemoglobin level is calculated.

Since two wavelengths are used in measuring (570 nm and 880 nm), the turbidity in a sample is automatically compensated for. Carboxyhemoglobin, leukocytosis, and turbidity do not interfere with the test.

The Analyzer is calibrated at the factory against the hemiglobincyanide (HiCN) method, which is the international reference method for the determination of the total hemoglobin concentration in blood.

Each Analyzer is delivered with an AC Adapter and one Control Cuvette.

If data output to a computer or printer is desired (*Figure 1B*), then a computer (PC) with a Windows (3.1/95/98/NT) operating system, and/or a compatible printer, and appropriate HemoCue connection cables will be needed (see *Section 2.4.4*).

***Figure 1B**: The Analyzer can interface with a variety of input and output devices*

1.3 Front Panel

The Analyzer's front panel contains an LCD display, a 26-button touchpad, including an "On" button which restarts the unit from automatic power-down mode (Battery Save Mode).

***Figure 1C**: Front display panel*

1.3.1 LCD Display Window

The display window can display four lines, each with 20 alphanumeric characters. The display will show measurement results, guidance information for the operator, and selection menus, coupled to the touchpad buttons, "A," "B," and "C."

1.3.2 Touchpad

The front panel has 26 buttons with tactile feedback, organized in five groups (see *Figure 1C*):

- **Group 1** is located immediately below the LCD display and it contains three buttons, "A," "B," and "C," which are used to select from varying menus shown on the display's bottom line. While the functions assigned to these buttons can vary, the user will notice that "A" is usually used to cancel or go back a step, "B" usually enables the user to change or update information on the display, and "C" will usually signify "Enter" or "OK."
- **Group 2** has black and red lettered buttons ("Patient Test," "QC Test," "Setup," and "STAT"), which are used to select function sequences.
- **Group 3** has buttons with white lettering which are used to review data (see *Section 1.6.6* for more information on Review and List functions). The "Review & List" and "Review Menu" functions review previously collected data and also include a touchpad sequence that allows erasure of the log memory. The "Prev" and "Next" arrow buttons are used to move the cursor back and forth in parameter fields during touchpad input or to scroll backward and forward through data points in the Analyzer memory.
- **Group 4** contains general purpose buttons. "Enter" executes the entry of a value or selection, and thus is an alternative to button "C" (OK). "Escape" will break any function or sequence and return to the "READY" state. The "On" button is used to restart after an automatic power-down.
- **Group 5** is for numeric input. The "Delete" button will erase the digit at the cursor location.

Note: *The Analyzer will only respond to buttons which are operational in a specific state. Pressing any other button will result in an audible error signal.*

1.3.3 Cuvette Holder

The cuvette holder, which is used to move the cuvette in and out of the photometer, has three positions:

- Completely pushed in — measuring position
- Pulled out to first detent — loading position
- Completely withdrawn — for cleaning

1.4 Top Side Panel

1.4.1 Data Communication Ports

The Analyzer inputs and outputs information via two RS-232 compatible serial output ports, located on the back of the unit. PORT 1 may be used to establish a two-way communications link to a host computer (PC) or an output-only connection to an 80 column printer. PORT 2 may be used for output to a small label-type printer (such as the optional HemoCue Small Printer) and for receiving input from a Bar Code Reader/Wand. *Chapter 9* provides detailed information regarding communications to and from the Analyzer.

***Figure 1D**: Top side panel*

1.4.2 Power Inlet Port

Power to run the Analyzer can come from either batteries or from the HemoCue 6V AC Adapter, which plugs into the Analyzer via the POWER INLET port. (See *Chapter 2* for more information).

1.4.3 On/Off Switch

The "ON/OFF" toggle switch powers on the device. Regardless of whether the Analyzer is powered by batteries or the AC Adapter, the "ON/OFF" toggle switch must be in the "ON" position in order for the Analyzer to function. When battery powered, there is an automatic shutoff after a user pre-setable time. Restart is accomplished by pressing the green "On" button on the front touchpad. The "On" button will only restart the unit from Standby when the "ON/OFF" switch is in the "ON" position.

1.5 Internal Features

1.5.1 Audible Tones

The Analyzer has built in audible tones, indicating different events:

- Measurement ready: A short signal
- Button pressed: A very short signal
- Correct reading from Bar Code Reader (BCR): A short signal
- Error occurrence: A long, low pitch signal

1.5.2 Real Time Clock (RTC)

The internal RTC has battery backup that will last for several years, even without external power. Once set, the RTC will keep track of date and time of day. However, all year information will be displayed, both on the display screen and in printouts, in 2-digit format.

1.6 Functional Features

1.6.1 "READY" State

This is the idle state of the Analyzer, when it is switched on and the cuvette holder is in the outer loading position. The Analyzer must display "READY" and the cuvette holder must be pulled out to the first detent in order to start a function sequence with a button in the left group on the touchpad (Group 2 in *Figure 1C*).

When the Analyzer is first turned on (either via the ON/OFF toggle switch or the "On" button on the front panel), the display will first read, "PLEASE, PULL OUT THE CUVETTE HOLDER."

After pulling the cuvette holder out to the first detent, the bottom line of the display will read, "SELFTEST." "SELFTEST" indicates that the Analyzer is undergoing an internal diagnostic check. This check will take approximately 15 seconds to complete. No testing with the Analyzer can be performed until the "SELFTEST" is completed and "READY" appears on the display. The Analyzer is now in the "READY" state.

When in "READY" state, the third line on the display shows the total amount of memory in the device and the number of free record locations ("MEM: ___" and "FREE: ___").

After "SELFTEST" has been completed, there are two special conditions where "READY" will not be displayed:

- "PAT. TEST LOCKED-OUT" means that one or more failing QC tests have locked out further patient tests (these QC tests must be successfully passed to resolve the lockout)

- "MEMORY FULL" also means that further measurements are precluded (the memory must be erased to solve this condition. See *Section 3.4*).

In both of these situations, several function buttons will be available for use in order to alleviate the problem, but patient measurements will not be allowed.

1.6.2 Quality Control Testing with Patient Test Lockout

Several types of Quality Control tests may be performed: Control Cuvette ("QCC"), Liquid Control Low Level ("QCL"), Liquid Control Normal Level ("QCN"), Liquid Control High Level ("QCH"), Other user-defined Quality Control test levels ("QCO"), Linearity tests ("LI*"), and Proficiency tests ("PT").

Using the Control Cuvette, the three liquid Controls, and other controls, the Analyzer supports a quality control scheme, with automatic Patient Test Lockout. To resolve the lockout, all desired QC tests set to "ON" in Setup Level 2 must be run and must obtain results within its specified range. The unlocked condition will last for the remainder of the current work shift, unless a test is repeated and fails.

When locked-out, a message, "PAT. TEST LOCKED-OUT" will be displayed. The list on the bottom line of the display will show which tests are currently required to unlock the instrument for use. For example, "RUN ALL QC TESTS," will be displayed if all QC tests are required. "RUN QCC, QCH," will be displayed if only the Quality Control Cuvette and High Liquid Control tests are required.

1.6.3 Critical Values

Critical values are user-defined in Setup Level 2. If a patient result is in the critical value range, there is an audible tone and "CRITICAL" appears on the display. Recognition of the critical value is required by pressing the "C" button.

1.6.4 Comment Codes

If the Comment Code feature has been enabled in Setup Level 2, the operator may attach a Comment Code to each measurement record. The Comment Code range is 1000-1099 and their meanings are user-defined by each facility. If no comment is entered, it is stored as 0 in the Analyzer's memory. (See *Appendix* for Bar Codes).

1.6.5 Maintenance Records

Maintenance Records are entered manually into the Analyzer's memory. User defined codes are used to denote specific maintenance actions; e.g., cleaning the optronic unit. The code range is 970-989. Each Maintenance Record is stored as type "ADJ" (adjust) in the Analyzer's memory. See *Section 10.6* for instructions on how to enter maintenance records. (See *Appendix* for Bar Codes).

1.6.6 Review and List Functions

The Review & List functions are used to review and print the information stored in the Analyzer memory. The buttons used are signified by white lettering. When the "Review & List" button is pressed, the last record is displayed. With the "Prev" and "Next" buttons, you can step back and forth in the list of stored records.

The button, "Review Menu," shows the current Review & List selection, e.g., "ALL TESTS," and a menu. From the menu, you may select "EXIT," "PRINT," or "SELECT."

With "SELECT," you narrow down the list of records displayed. You may select for display the specific Type of Record, Operator, Patient, or Control Lot within a specified Time frame.

Data erasure can be performed manually (i.e., initiated from the Analyzer's touchpad) after the "PRINT" command has initiated printing of the memory's data or has simulated printing (see *Section 3.4*).

1.6.7 Data Memory

The Analyzer records all measurements in its internal memory. Each record contains Instrument Serial Number, Date, Time, Type of Record, QC data where applicable and Result of the test. If enabled in Setup Level 2, Operator ID, Identity (Patient ID or Control Lot) and Cuvette Batch data are also stored and a Comment Code may be attached to each record. The internal memory may even be used as a maintenance log-book, since specific Maintenance Records with a code denoting the operation may be entered manually or with the help of a Bar Code Reader. The memory also records whenever Setup Levels are entered and changes to Setup Levels 1 or 2 have been made. Other record types that don't store a measurement value also use a code to ease identification. The data stored in the memory can never be changed or modified.

Data records use the following type designators and identity codes:

• Patient Test	PAT	
• STAT (Short Turn Around Time) Test	STA	
• Control Cuvette Test	QCC	
• Control Low Level Test	QCL	
• Control Normal Level Test	QCN	
• Control High Level Test	QCH	
• Control Test, Other	QCO	
• Linearity Test Begin	LIB	
• Linearity Tests 1 - 5	LI1 through LI5	
• Proficiency Test	PT	
• Overrange on result (displayed as "OVERRANGE")	Any type as above	Code 999
• Aborted Test (displayed as "ABORTED")	Any type as above	Code 990
• Erroneous measurement	ERR	Codes 900-908
• Hardware Error	ERR	Codes 910-930
• Maintenance record/Adjust	ADJ	Codes 970-989
• Critical Value	CRITICAL (shown on PAT & STA)	
• Enter Password Protected Setup levels	SET	
• Update Quality Control info.	MQC, MQL, MQN, MQH, MQO	
• Update Cuvette Batch	MCB	
• Bad Record	BAD	

In this chapter, you will install the power source(s) and connect the Analyzer to optional data output and input devices.

2.1 Install Power Source

2.1.1 Batteries

The battery compartment is located on the rear/bottom panel of the Analyzer. Open the battery compartment by moving the compartment's latch to the right and, at the same time, lifting up the cover at the notch in the cover's upper left-hand corner.

Place five batteries, type AA (or R6), in the battery compartment, observing the indication of polarity in the battery holder. Replace the cover. New batteries can operate continuously for 100-150 hours. If battery powered, batteries can be readily conserved by switching "OFF" the Analyzer with the "ON/OFF" toggle switch (located on the top side panel) between measurements.

Figures 2A and ***2B***: *Back Panel shown with and without Battery Cover in place*

Another feature that can be used while battery powered is the *Battery Save Mode*. With this feature, the Analyzer can be set to automatically power-down if the instrument has not been used within a pre-set length of time (for more information see *Section 3.8* step 30).

The Analyzer has built-in supervision of the battery status, with a warning ("LOW BAT") on the display when batteries are weak (<5.4V). If the voltage drops to the point where accurate measurements cannot be made, the Analyzer automatically switches off and cannot be used.

2.1.2 AC Adapter

Insert the AC Adapter's power plug into the POWER INLET on the top side panel of the Analyzer (see *Figure 1D*). Plug the AC Adapter into a standard electrical outlet.

WARNING: **Use ONLY the HemoCue 6V AC Adapter with the Analyzer.** Other brands of AC Adapters may be able to physically plug into the Analyzer, but can seriously damage the Analyzer or cause **risk of fire**.

IMPORTANT: *When switching from battery power to the AC Adapter, turn off the Analyzer first, using the "ON/OFF" toggle switch on the top side panel. The batteries can be left inside the battery compartment when running the Analyzer from an AC source without depleting the batteries.*

2.2 Connect the Analyzer to Desired Data Input/Output Devices

Figure 2C shows the cables used to interface the Analyzer with various data input (e.g. bar code wands) and output (printers, PC's) devices.

PORT 1 of the Analyzer may be used to establish a two-way communications link to a PC, or alternatively, an output-only connection to an 80 column printer.

PORT 2 may be used for output of a single patient record to a small (label) printer (such as the HemoCue Small Printer) and for receiving input from an external input device; e.g., a Bar Code Reader/Wand (BCR).

***Note*:** *For technically detailed information on the Analyzer's communication specifications (including connector pin-outs, communication block structures, port listings, and compatibility requirements), please refer to Chapter 9.*

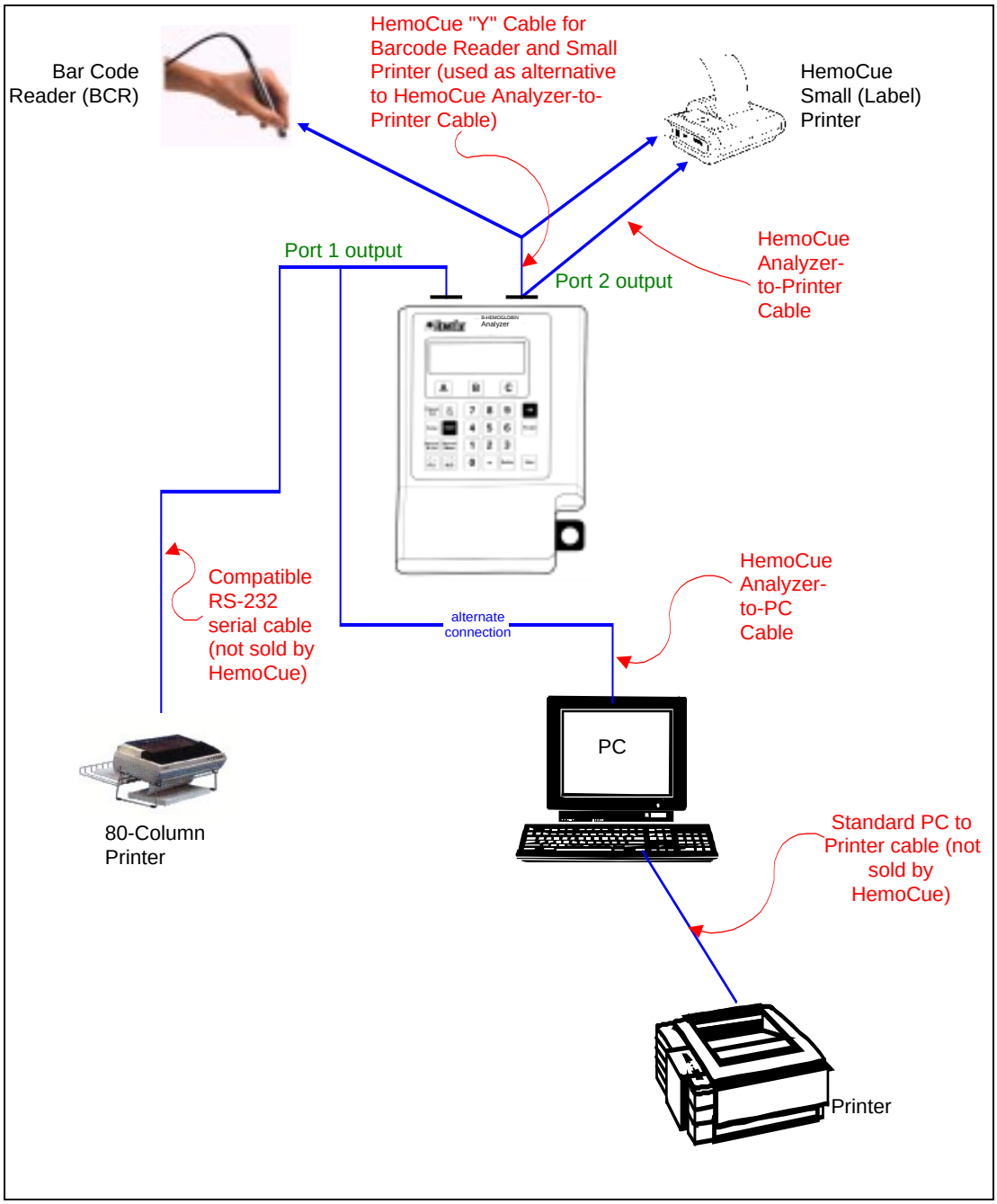

Figure 2C: *Interconnection of the Data Analyzer to Peripheral Devices*

2.2.1 Data Output from PORT 1 to a PC

Use the HemoCue Analyzer-to-PC Cable to connect PORT 1 of the Analyzer to the serial port of a PC.

If a serial connecting cable other than the HemoCue Analyzer-to-PC Cable is used, ensure that the cable meets the connector (DB9 type) and RS-232 pin-out requirements of PORT 1 specified in *Section 9.2*.

PORT 1 establishes a two-way communication link between the Analyzer and a PC which is controlled from the PC by the HemoCue Analyzer Communications software. The characteristics of these communications are configured in the Analyzer's Setup Level 1 (see *Section 3.7*) and in the HemoCue Analyzer Communications Software (which has been installed into the PC).

2.2.2 Data Output from PORT 1 to an 80-Column Printer

Use a cable with a compatible pin-out to the Analyzer's PORT 1 (see *Section 9.2*) to connect the port to the respective serial port of an 80-column printer with RS232 serial interface. The printer can be connected to PORT 1 in place of connecting a PC (they cannot be connected simultaneously to PORT 1). With the printer connected to PORT 1, a send-only communications link can be established from the Analyzer to the printer.

PORT 1's communication parameters can be programmed in Setup Level 1 to output information to the 80-column printer (see *Section 3.7*). See *Table 9a* for PORT 1's allowable Communication Parameters.

2.2.3 Data Output from PORT 2 to a Small (Label) Printer

Use the HemoCue Analyzer-to-Printer Cable (and the HemoCue "Y" Cable if also connecting a Bar Code Reader) to connect PORT 2 of the Analyzer to the HemoCue Small Printer or a similar 20-column printer with RS232 serial interface. Each Analyzer measurement record is immediately printed when the result is ready. However, if desired, the data output from PORT 2 may be completely disabled in Setup Level 1 (see *Section 3.7*).

2.2.4 Data Input to PORT 2 from a Bar Code Reader (BCR)

A serial cable, or the HemoCue "Y" Cable, may be used to connect PORT 2 to a Bar Code Reader with a compatible RS-232 interface (see *Section 9.2* for RS232 pin-outs to PORT 2). The BCR may get its power from the Analyzer via pin 9 of the RS232 connector, as long as the current required by the reader does not exceed 20 mA.

With a BCR connected to PORT 2, a receive-only communications link is established. This may be used to enter operator and patient data in a quick and reliable way, i.e., it is an alternate way for the operator to enter numeric information instead of the Analyzer touchpad. The BCR can also be used to read cuvette and control information, as well as comment and maintenance code numbers. Data from the BCR is received through a RS232 receiver which is always activated while the Analyzer is powered on.

2.3 Install PC Communication/Data Analysis Software

HemoCue has developed computer software which enable:

a) downloading of data from the Analyzer to a PC (via the HemoCue Analyzer Communication Software)
b) analysis of the downloaded data (via the HemoCue Data Analysis Software).

Please refer to the User Guides which accompany these software for minimum PC installation requirements, software set-up steps and instructions for use.

All communications between the Analyzer and a PC computer are controlled from the PC. The measurement data is stored in memory and is transferred to the PC on the request of the communications software. For communication parameters, see *Chapter 9.*

2.4 System Accessories

2.4.1 Microcuvettes*

B-Hemoglobin microcuvettes are available in 200/box (50/vial) or 100/box (25/vial).

2.4.2 Quality Controls*

- *Control Cuvette*

  The Control Cuvette, which is an optical interference filter, is used daily to verify that the calibration of the Analyzer is stable (i.e., not changing from day to day). The assayed value of the Control Cuvette has been determined in conjunction with a specific Analyzer.

- *Hemolyzed Controls*

  The HemoCue hemolyzed control (bovine hemolysate) is available in three levels (low/normal/high).

- *Linearity Products*

  Used for performing linearity studies or calibration verification. The HemoCue Linearity product (bovine hemolysate) has five levels.

2.4.3 Miscellaneous*

- 6V AC Adapter
- HemoCue Cleaner (for cleaning the optronic unit compartment inside the Analyzer)
- HemoCue Hemoglobin Calibrator
- HemoCue Safety Lancets (for capillary punctures)

2.4.4 Accessories for Data Output/Input to the Data Management Analyzer*

- HemoCue Small Printer
- HemoCue Bar Code Reader
- HemoCue Analyzer-to-Printer Cable (to connect to small printer)
- HemoCue Printer Kit (small printer, cable, and printer's AC adapter)
- HemoCue Analyzer-to-PC Cable
- HemoCue Analyzer Communications Software including Users Guides
- HemoCue Data Analysis Software including Users Guides
- Hemoglobin Data Management Start Up Kit (includes HemoCue Software for Communication and Data Analysis, HemoCue Software User Guides, and Analyzer-to-PC cable)
- HemoCue "Y" Cable (for connecting Analyzer to a Bar Code Reader (for data input) and Small Printer (data output))

** Please contact your local HemoCue distributor for ordering information.*

IMPORTANT: *Accessory equipment connected to* PORT 1 *and/or* PORT 2 *of the Analyzer must be certified according to appropriate IEC standards (e.g., IEC 950 for data processing equipment). Furthermore, all configurations must comply with the International System Standard IEC 601-1. Operators who connect additional equipment to the Analyzer's signal input or signal output ports configure a "medical system" and are, therefore, responsible for ensuring that this system complies with IEC 601-1. If in doubt, consult HemoCue Technical Support or your local HemoCue representative.*

In this chapter, you will configure the Analyzer to meet your specific clinical and communications requirements. The Analyzer can be configured in two ways:

1) Directly from the Analyzer (this is described in this chapter).
2) Via a PC (refer to HemoCue Communication software for configuration set-up instructions).

The Setup functions provide significant flexibility by allowing the user to determine the degree of password security desired and to configure each control parameter setting.

Analyzer setup is divided into two levels:

- Setup Level 1 is used to set the time, date, and communications port parameters.
- Setup Level 2 is used to select operating conditions.

Both levels of setup are started by pressing the "Setup" button on the touchpad, but each level has its own password. The Setup levels are designed as step-through lists.

3.1 Prepare for Programming the Setup Levels

- Power on the Analyzer using the "ON/OFF" switch on the top side panel. The display panel will then ask you to pull out the Cuvette Holder.

- Pull out the Cuvette Holder to the first (loading) position.

- SELFTEST- The Analyzer requires 15 seconds to undergo an internal diagnostic check. This begins as soon as the Cuvette Holder is pulled out into the loading position. "SELFTEST" will be shown in the lower left hand corner of the display.

- "READY" state - The display will show "READY" when the Analyzer has completed its self check and is now in "READY" state. An occasional flicker may be observed on the display, which is due to an update of the display information.

  In "READY" state, the display will also indicate the total number of record positions available in memory and the total number of free record positions left in memory. An example of the memory display is shown in *Figure 3A*. The Analyzer can hold approximately 1,000 test results.

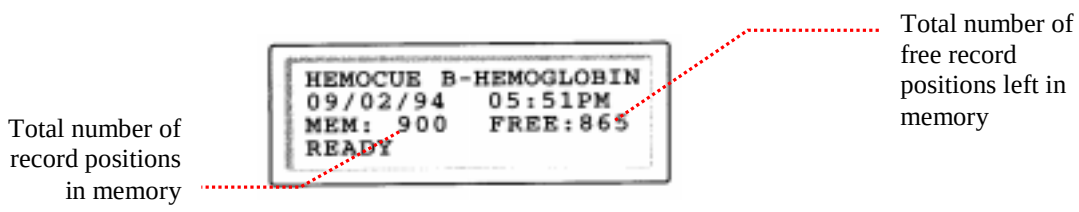

***Figure 3A**: Analyzer Display in* "READY" *state*

IMPORTANT: *If you see* "PAT. TEST LOCKED OUT," *instead of* "READY," *it means that you have some mandatory QC tests which are due. If you see* "MEMORY FULL," *you will need to erase the Analyzer's memory before proceeding with patient measurements (see Section 3.4). However, you can still make changes to both Setup Levels 1 and 2.*

3.2 Setup Level 2 - Overview

Since Setup Level 2 configures the Analyzer's basic operating conditions (such as the time and date format), it should be run before Setup Level 1. There are two ways to enter Setup Level 2 information into the Analyzer:

1) Manually, using the Analyzer's touchpad.

2) Via a PC (which has been installed with the HemoCue Analyzer Communication Software) connected to PORT 1 of the Analyzer.

See the software Users Guide for detailed directions on transferring setup information via the software program.

In Setup Level 2, the following parameters can be set:

- QC testing requirements, including automatic Patient Test lock-out conditions
- Shift Length for each QC level is assigned individually
- First Shift start time
- Critical Values (minimum and maximum)
- Operator ID parameters and requirements*
- Patient ID parameters and requirements*
- Units of measurement for Analyzer
- Date and time format
- Enable/disable Comment Codes*
- Enable/disable STAT tests
- Memory erasure conditions
- Idle time interval before automatic power down (battery saver feature)
- Passwording for Setup Level 1
- Passwording for Setup Level 2
- Passwording for entering/changing QC information
- Option to select Analyzer display of QC results as Pass/Fail or numeric result (downloaded data will show measured numeric values)
- Storage requirements for Cuvette batch parameters and Password for changing Cuvette batch parameters*
- Passwording for memory erasure

***** *Requires memory erasure to make changes to these parameters.*

3.3 Setup Level 2 Parameters Which Require Memory Erasure to Change

If this is the initial programming of the Analyzer or the display shows that the total memory ("MEM:") is equal to the free memory ("FREE:"), then proceed to *Section 3.6* to program Setup Level 2.

However, if the Analyzer has been setup previously and you wish to change the following parameters, then *the Analyzer memory must first be erased*:

- Operator ID, setting minimum and maximum digits
- Patient ID, setting minimum and maximum digits
- Enable/disable Comment Codes
- Enable/disable Cuvette batch parameters

To erase the Analyzer memory, proceed to *Section 3.4*.

Note: *If you need to save any data points prior to erasing the memory, then follow appropriate instructions in the Communications Software Users Guide for downloading data to a PC.*

3.4 Erasing the Analyzer Memory

IMPORTANT: *In order to minimize the chance of data loss, the Analyzer is programmed to print out all data to an 80-column printer connected to* PORT 1*, before erasing the memory. However, in order to erase the memory when the Analyzer is not connected to a printer, then it will be necessary to select* "YES" *for the* "ERASE WITHOUT PRINT" *option in Setup Level 2. If you are not connected to a printer and are not sure whether* "ERASE WITHOUT PRINT" *has been enabled in Setup Level 2, then it will be necessary for you to go through Setup Level 2 and check this setting prior to erasing the memory. Follow the instructions for programming Setup Level 2 in Section 3.6 prior to proceeding with memory erasure. Then, return to this section and proceed with the following steps*:

1. While in "READY" menu, press the "Review and List" button on the touchpad.

2. Press the "Review Menu" button. The display will show "REVIEW, ALL TESTS."

3. Press the "B" button to select "PRINT." If the printer is not connected there will be a beep and the display will read "REVIEW, CHECK PRINTER CONNECTION." Press "Enter" or "C" (OK).

4. The display will read "REVIEW PRINTING…. PLEASE WAIT." The display will automatically change to "REVIEW, ERASE MEMORY?" If you now wish to erase the memory without actually printing, press the "B" button to change "NO" to "YES," then press "Enter" or "C" (OK).

5. The display will then read, "REVIEW, ERASURE PASSWORD:" Enter the password that is required to manually erase data from the data management analyzer. The default password for erasing data is "0000." This password can be customized in Setup Level 2. Enter the erasure password and press "Enter" or "C" (OK). The data will now be erased from the Analyzer.

6. In order to now return to the "READY" menu, either press the "Escape" button on the touchpad or press the "A" button to exit. The numbers listed after Memory ("MEM:") and the Free Memory ("FREE:") on the Analyzer display should now be equal.

3.5 Setup Instructions - Overview

Sections 3.8 and *3.9* provide detailed instructions for setting up the Analyzer. They should be used by those who require a point by point description of each setup step.

Remember, as you step through these Setup Levels:

- Setup Level 2 should be run *before Setup Level 1* if you want to select/change the time and date formats.
- Whenever the "A" button has "CANCEL" displayed above it, you can use "A" (CANCEL) to move backwards through the Setup Level sequence steps.
- Selecting "B" (CHANGE) will allow you to make changes to the parameter (will only appear if changes are allowed and the cursor will flash on the changing parameter).
- Pressing "Enter" or "C" (OK) will select the current setting of the parameter and move forward to the next Setup Parameter in the sequence.
- Pressing "Escape" will exit the Setup Level 2 sequence and return you to the ″READY″ display. All changes made will be saved.
- The arrow ("Prev" and "Next") buttons can be used to position the cursor while inputting data.
- Whenever a QC test is made mandatory (ON), it means that it *must be executed with a successful result during the current work shift* to prevent getting a "PAT. TEST LOCKED OUT" display. It also means that the mandatory test must be executed with a successful result before proceeding to patient testing.

3.6 QUICK Instructions for Programming Setup Level 2

1. Certain parameters in Setup Level 2 require a cleared (erased) memory to be changed. If you want to make changes to the "OPERATOR ID" or "PATIENT ID" minimum or maximum digits, turn on/off the Comment Codes, or change the requirements for Cuvette Batch passwording, then you will need to erase the Analyzer's memory first. Go to *Section 3.4* to do this. After erasing memory, proceed to next step below.

   ***Note*:** *Whenever Setup Level 2 is entered, Time, Operator ID (if mandatory) and Level # will be documented in the Analyzer memory*.

2. Press "Setup" button and enter "OPERATOR ID" (***Note:*** *On initial setup,* "OPERATOR ID" *is defaulted as not mandatory, therefore, no prompt appears for* "OPERATOR ID").

3. Enter "2345" as password ("2345" is the default password; this can be changed later in Setup Level 2).

4. "QC CONTROL CUVETTE:" If you require QC using the Control Cuvette (QCC), select "ON."

5. "QCC SHIFT LENGTH (HOURS):" OFF, 1, 2, 3, 4, 6, 8, 12, or 24.

6. "QC LIQUID CONTROL, LOW LEVEL:" If you require low level QC (QCL), select "ON."

7. "QCL SHIFT LENGTH (HOURS):" OFF, 1, 2, 3, 4, 6, 8, 12, or 24.

8. "QC LIQUID CONTROL, NORMAL LEVEL:" If you require normal level QC (QCN), select "ON."

9. "QCN SHIFT LENGTH (HOURS):" OFF, 1, 2, 3, 4, 6, 8, 12, or 24.

10. "QC LIQUID CONTROL, HIGH LEVEL:" If you require high level QC (QCH), select "ON."

11. "QCH SHIFT LENGTH (HOURS):" OFF, 1, 2, 3, 4, 6, 8, 12, or 24.

12. "QC LIQUID CONTROL, OTHER LEVEL:" If you require other QC Control testing (QCO), select "ON."

13. "QCO SHIFT LENGTH (HOURS):" OFF, 1, 2, 3, 4, 6, 8, 12, or 24.

14. Enter Start Time of First Shift ("FIRST SHIFT STARTTIME").

15. Enter "CRITICAL VALUES" (minimum and maximum).

16. Make "OPERATOR ID" mandatory? (Mandatory/Not Mandatory)

17. Set "OPERATOR ID" minimum and maximum digits (range: 1 - 10). Requires memory erasure before making changes.

18. Should Analyzer clear the "OPERATOR ID" before each test? YES/NO (YES preferred if you have a variety of operators using the device).

19. Make "PATIENT ID" mandatory? (Mandatory/Not Mandatory).

20. Set "PATIENT ID" minimum and maximum digits (range: 1 - 15). ***IMPORTANT*****:** *If liquid controls are used, the number of digits in the control's lot number must be within the minimum and maximum range of the* "PATIENT ID." *Requires memory erasure before making changes.*

21. Should Analyzer clear the "PATIENT ID" before each test? (YES/NO) (YES preferred if using the device on a variety of patients).

22. Select desired "CONCENTRATION UNITS" of measurement (G/DL, MMOL/L, or G/L).

23. Select desired "DATE FORMAT" (MM/DD/YY, DD.MM.YY, or YY-MM-DD).

24. Select desired "TIME FORMAT" (24H or 12 AM/PM).

25. Entry of "COMMENT CODE" desired with each measurement? (YES/NO). Requires memory erasure before making changes.

26. "STAT TEST" allowed? (YES/NO).

27. Allow erasure of memory without printing ("ERASE WITHOUT PRINT")? (YES/NO). ***IMPORTANT*****:** "YES" *must be selected in order to erase the memory from a standalone Analyzer (which is necessary if you need to make changes to any of the parameters noted in the first step of this list).*

28. Select the automatic "POWERDOWN TIME" when running on batteries: 5, 10, 15, 20, 25, or 30 minutes.

29. Set Password for Setup Level 1 ("PASSWORD LEVEL 1"). ***IMPORTANT*****:** *If you make changes, be sure to record the new password. Also, do not use the same password for Setup Levels 1 and 2.*

30. Set Password for Setup Level 2 ("PASSWORD LEVEL 2"). See comments above.

31. Set Password for changing QC information ("PASSWORD QC"). ***IMPORTANT*****:** *If you make changes, be sure to record the new password.*

32. Should the Analyzer display QC measurements ("DISPLAY QC MEASUREMENT")? If "YES" is selected, then the measured value, target value and "PASS" or "FAIL" will be displayed following a QC measurement. If "NO" is selected, then only "PASS" or "FAIL" and the target value will be displayed. ***Note*****:** *Downloaded data will always include the numeric QC measurement result.*

33. Set Password for changing Cuvette Batch information ("CUV. BATCH PASSWORD"). ***IMPORTANT*:** *Requires memory erasure before making changes. If you make changes to password, be sure to record new password. In this step, you can also select options for using No Password or turning off the function altogether* ("OFF").

34. Set Password for memory erasure ("PASSWORD ERASURE"). ***IMPORTANT*:** *If you make changes, be sure to record the new password.*

3.7 QUICK Instructions for Programming Setup Level 1

1. Press "Setup" button.
2. Enter "OPERATOR ID, " if mandatory (the # of digits required is set in Setup Level 2).
3. Enter "1234" as password.
4. Set "DATE."
5. Set "TIME."
6. Set Communication Mode for PORT 1 ("PORT 1 COMM MODE") (PC Batch or PC Online).
7. Set Baud Rate for PORT 1 ("PORT 1 BAUDRATE") (1200, 2400, 4800, or 9600).
8. Set Data Bits for PORT 1 ("PORT 1 DATABITS") (7 or 8).
9. Set "PARITY" for PORT 1 (No, Odd, or Even).
10. Set data output option for PORT 2 (No Printer or Small Printer).

3.8 DETAILED Instructions for Programming Setup Level 2

Table 3a – Programming Setup Level 2

Step #	Setup Parameter	Choices	Defaults	Setup Level 2 - Action
1.	Start Setup		n/a	Press the "Setup" button on the touchpad.
2.	Enter Operator ID, if mandatory		n/a	Press "C" (OK) or "Enter."
3.	Enter Password		2345	Press buttons "2345" on the touchpad. Press "C" (OK) or "Enter."
4.	Require use of QC Control Cuvette?	OFF, ON	OFF	Decide if measuring the Control Cuvette is a mandatory QC test. Whenever a test is made mandatory (ON), it means that it must be executed with a successful result during the current work shift to prevent getting a "PATIENT TEST LOCKED OUT" display. To change setting, press "B" and to select displayed setting, press "C" (OK) or "Enter."
5.	Set QC Control Cuvette Shift Length (hrs)	OFF, 1, 2, 3, 4, 6, 8, 12, 24	OFF	Select work shift length. When set at "OFF," a failed test of a mandatory Control will lock-out patient testing instantly. To step through the selection list, press "B," and to select the displayed setting, press "C" (OK) or "Enter."
6.	Require QC Liquid Control, Low Level?	OFF, ON	OFF	Decide if measuring liquid controls at low level is a mandatory QC test. See comment in Step 4 regarding timing of mandatory QC tests.
7.	Set Shift Length for QC Control, Low Level	OFF, 1, 2, 3, 4, 6, 8, 12, 24	OFF	Select work shift length. When "OFF," a failed test of a mandatory Control will lock-out patient testing instantly.
8.	Require QC Liquid Control, Normal Level?	OFF, ON	OFF	Decide if measuring liquid controls at normal level is a mandatory QC test. See comment in Step 4 regarding timing of mandatory QC tests.
9.	Set Shift Length for QC Control, Normal Level	OFF, 1, 2, 3, 4, 6, 8, 12, 24	OFF	Select work shift length. When "OFF," a failed test of a mandatory Control will lock-out patient testing instantly.
10.	Require QC Liquid Control, High Level?	OFF, ON	OFF	Decide if measuring liquid controls at high level is a mandatory QC test. See comment in Step 4 regarding timing of mandatory QC tests.
11.	Set Shift Length for QC Control, High Level	OFF, 1, 2, 3, 4, 6, 8, 12, 24	OFF	Select work shift length. When "OFF," a failed test of a mandatory Control will lock-out patient testing instantly.
12.	Require QC Control, Other Level?	OFF, ON	OFF	Decide if measuring controls at "other" level is a mandatory QC test. See comment in Step 4 regarding timing of mandatory QC tests.
13.	Set Shift Length for QC Control, Other Level	OFF, 1, 2, 3, 4, 6, 8, 12, 24	OFF	Select work shift length. When "OFF," a failed test of a mandatory Control will lock-out patient testing instantly.

Table 3a – Programming Setup Level 2				
Step #	**Setup Parameter**	**Choices**	**Defaults**	**Setup Level 2 - Action**
14.	Set First shift, start time		12:00 AM	Select start time of first work shift. (***IMPORTANT*:** *If controls are tested prior to the indicated start time of the first shift, the operators will be locked out from performing patient testing after the first shift start time is reached again. To insure that this doesn't happen, select a shift start time after which the controls will be performed.)*
15.	Set Critical Values	MIN___, MAX ___	0, 25.5 (g/dl) 0, 15.8 (mmol/l) 0, 255 (g/l)	Select minimum and maximum values. Patient results will be flagged as critical if they fall below the min. value selected or above the max. value selected. ***Note*:** *When a patient result is flagged as* "CRITICAL," *the* "C" *button must be pressed to continue.*
16.	Require entry of Operator ID?	Not Mandatory, Mandatory	Not Mandatory	Decide whether "OPERATOR ID" is to be required.
17.	Set Min. digits of Operator ID	Range: 1-10	3	The data in the Analyzer's memory must be erased prior to changing this setting. Select minimum number of digits in an "OPERATOR ID." To select the minimum number of digits, indicate the correct number at the flashing cursor.
18.	Set Max. digits of Operator ID	Range: 1-10	5	The data in the Analyzer's memory must be erased prior to changing this setting. Select maximum number of digits in an "OPERATOR ID." To select the maximum number of digits, indicate the correct number at the flashing cursor.
19.	Clear Operator ID before test?	YES, NO	YES	Decide if "OPERATOR ID" is to be cleared before each test. "YES" is preferred if there are a variety of operators using the Analyzer. If "NO" is selected, then the last "OPERATOR ID" entered will be recalled automatically.
20.	Require entry of Patient ID?	Not Mandatory, Mandatory	Not Mandatory	Decide if a "PATIENT ID" is to be required.
21.	Set Min. digits for Patient ID	Range: 1-15	5	The data in the Analyzer's memory must be erased prior to changing this setting. Select a number from 1 to 15 as the minimum number of digits for a "PATIENT ID." ***IMPORTANT*:** *If liquid controls are used, the number of digits in the control's lot number must be within the minimum and maximum range of the* "PATIENT ID."
22.	Set Max digits for Patient ID	Range: 1-15	10	The data in the Analyzer's memory must be erased prior to changing this setting. Select a number from 1 to 15 as the maximum number of digits for the "PATIENT ID." ***IMPORTANT*:** *If liquid controls are used, the number of digits in the control's lot number must be within the minimum and maximum range of the* "PATIENT ID."

Table 3a – Programming Setup Level 2				
Step #	**Setup Parameter**	**Choices**	**Defaults**	**Setup Level 2 - Action**
23.	Clear Patient ID before test?	YES, NO	YES	Decide if "PATIENT ID" is to be cleared before each test. If "NO" is selected, then the last "PATIENT ID" entered will be recalled automatically.
24.	Set Concentration Units	G/DL, MMOL/L, G/L	G/DL	Decide which unit of measurement to use.
25.	Set Date Format	MM/DD/YY, DD.MM.YY, YY-MM-DD	MM/DD/ YY	Select the desired "DATE" format. Year entry is two digits only. Thus, the year 2000 is represented by "00."
26.	Set Time Format	12AM/PM, 24 H	12AM/PM	Select the desired "TIME" format.
27.	Comment Code used?	OFF, ON	OFF	The data in the Analyzer's memory must be erased prior to changing this setting. Decide if a comment code will be attached to measurement result when it is stored. The comment code range is "1000-1099." If no comment is entered, it is stored as "0."
28.	STAT Test Allowed?	YES, NO	YES	Decide if "STAT" tests are allowed. If allowed, operators will be able to perform patient testing and override the requirement of performing any mandatory QC tests. The "PATIENT ID" is not required to be entered, even if mandatory, to perform the "STAT" test, but the opportunity to enter the "PATIENT ID" will be displayed following the test results.
29.	Erase without Print?	YES, NO	NO	Decide if it will be possible to erase the memory without a previous verified printout of the stored data. ***IMPORTANT***: "YES" *must be selected in order for the operator to erase the memory from a stand alone Analyzer (not connected to a PC).*
30.	Power-Down Time (min.)	5, 10, 15, 20, 25, 30	15	Specify the time from the last operator input (or PORT 1 activity) until automatic power down. This will allow you to conserve the batteries. (***Note***: *To turn the Analyzer back on, press the* "ON" *button on the touchpad. Wait for the Selftest to be completed)*. The power down function only works when running on batteries.
31.	Set Password for Level 1	3-6 digits	1234	Set the security password for Setup Level 1. (***Note***: *You cannot use the same password for Setup Level 1 and Setup level 2. If you do, you will not be able to enter Setup Level 1).* If you change any of the defaulted passwords, remember to document it, so those secured functions can be entered later.
32.	Set Password for Level 2	3-6 digits	2345	Set the security password for Setup Level 2.

Table 3a – Programming Setup Level 2				
Step #	**Setup Parameter**	**Choices**	**Defaults**	**Setup Level 2 - Action**
33.	Set Password for QC information	3-6 digits	0000	The Quality Control (QC) password is required to change anything regarding the quality control lot numbers, expiration dates, and values. Operators will be locked out if they attempt to use outdated QC material.
34.	Display QC Measurements?	YES, NO	YES	If "NO" is selected, only "PASS" or "FAIL" and the target value will be displayed following performance of a QC test. If "YES" is selected, then both the measured value and "PASS" or "FAIL" will be displayed. This will also be displayed during the "Review and List" function. When the data is downloaded to a PC or printer, the actual test result value will always be transmitted.
35.	Set Password option for Cuvette Batch information	"CUVETTE BATCH PASSWORD: ____," "NO PASSWORD," and "OFF"	OFF, 0000	In order to make any changes to this parameter, the memory must first be erased. If memory has not been erased, the operator will not see a flashing cursor on the displayed setting. Once the memory has been erased, then the operator has 3 choices: a) turning off the function altogether and then the Analyzer will not request the cuvette batch number or expiration date during Patient Testing (select "OFF"). If this function is turned "ON," the operators will be locked out if they attempt to use outdated cuvettes, b) Setting a password to change cuvette batch parameters. A valid password consists of 3 to 6 digits (select "CUVETTE BATCH PASSWORD"), and c) No password protection for this function; i.e., allowing changing of the Cuvette Batch number and expiration without a password (select "NO PASSWORD").
36.	Set Password for Memory Erasure	3-6 digits	0000	A password is required to manually erase the database memory in the Analyzer.

3.9 DETAILED Instructions for Programming Setup Level 1

In Setup Level 1, the following parameters can be set:

- "TIME"
- "DATE"
- Parameters for PC or printer communications on PORT 1
- Enable immediate printout of each measurement result to PORT 2

Table 3b – Programming Setup Level 1				
Step #	**Setup Parameter**	**Choices**	**Defaults**	**Setup Level 1 - Action**
1.	Enter Setup		n/a	Press the "Setup" button on the touchpad.
2.	Enter Operator ID, if mandatory		n/a	Press "C" (OK) or "Enter."
3.	Enter Password		1234	Press buttons "1234" on the touchpad. Press "C" (OK) or "Enter."
4.	Set Date		n/a	Set "DATE" by entering a digit where the active cursor is. The cursor moves automatically or it can be moved by the arrow buttons on the touchpad. The "DATE" format used is set in Setup Level 2. To enter/accept displayed date, press "C" (OK) or "Enter."
5.	Set Time		n/a	Set "TIME" by entering a digit where the active cursor is. The cursor moves automatically or it can be moved by the arrow buttons. Input hours and minutes with two digits each in 24 or 12 hours format, as shown on the format line. Change AM/PM with "B." To enter/accept displayed time, press "C" (OK) or "Enter."
6.	Set Comm. Mode for PORT 1	PC Batch, PC Online	PC Batch	Select type of PC communications for PORT 1 of the Analyzer. PORT 1 is the port that is connected to your PC or laptop computer. Select PC Batch (default) or press "B" (change) for PC Online, then press "C" (OK) or "Enter." (See *chapter 9* for more details).
7.	Set Baud Rate for PORT 1	1200, 2400, 4800, 9600	9600	Select the communications speed on PORT 1. Your choice will be dependent on the communication requirements of the device that you are connecting the Analyzer to. Press "B" (change) to scroll through available baud rates. After selecting desired baud rate, press "C" (OK) or "Enter."
8.	Set Data Bits for PORT 1	7, 8	8	Select number of data bits on PORT 1 communications.
9.	Set Parity for PORT 1	NO, EVEN, ODD	NO	Select parity for PORT 1 communications.
10.	Set data output option for PORT 2	NO PRINTER, SMALL PRINTER	NO PRINTER	The only available option on PORT 2 is to designate if you are using a small printer to print results. The default selection is NO Printer. If you are using a small printer, press "B" to change to "SMALL PRINTER," then press "C" (OK) or "Enter."

This chapter will guide you through the various types of Quality Control (QC) testing which can be performed on the Analyzer.

4.1 Control Testing - Overview

The Analyzer is delivered calibrated against the Hemiglobincyanide (HiCN) method which is the ICSH reference (International Committee for Standardization in Haematology) method for the determination of the total hemoglobin concentration in blood. However, a facility may want to perform calibration verification on an Analyzer. Calibration verification is the process of assaying reference standards or calibration materials in the same manner as patient samples to confirm that the calibration of the Analyzer has remained stable. See *section 2.4.2* for available HemoCue controls.

As described in *Chapter 3,* the operator must specify which QC tests will be required and the specified period between performing mandatory QC tests. These requirements are set in Setup Level 2 (see *Section 3.6*).

Several types of Quality Control tests may be performed: Control Cuvette ("QCC"), Liquid Control Low Level ("QCL"), Liquid Control Normal Level ("QCN"), Liquid Control High Level ("QCH"), Control Other Level ("QCO"), Linearity tests ("LI*," where * indicates the linearity level), and Proficiency tests ("PT").

Using the Control Cuvette and the three liquid Controls, the Analyzer supports a quality control scheme, with automatic Patient Test Lockout. To inhibit lockout, each QC test which has been user-set to "ON" in Setup Level 2 must be run and must obtain results within its specified range. The unlocked condition will last for the remainder of the current work shift, unless a test is repeated and fails.

When locked-out, a message, "PAT. TEST LOCKED-OUT, RUN _____" will be displayed. After the word "RUN," the list of all the tests currently required to unlock the instrument will be displayed. For example, if QCC and QCL are the only tests required, (and have not been run successfully yet), then the display will read: "PAT. TEST LOCKED-OUT, RUN QCC, QCL."

Figure 4A: *Analyzer shown with Control Cuvette in place and HemoCue Liquid Controls*

4.2 QCC Test: Using the Control Cuvette

The Control Cuvette provided is specifically matched to the Analyzer and is intended for use only with that particular Analyzer. The serial number on the Control Cuvette should always match the serial number on the back panel of the Analyzer. The designated Control Cuvette should not be used in another Analyzer.

The Control Cuvette is used daily prior to patient testing to verify that the calibration of the Analyzer is stable (i.e., not changing from day to day). Values obtained should not deviate from the assigned value on the Control Cuvette card (included in the Control Cuvette's storage box) by more than ± 0.3 g/dl (± 0.2 mmol/l, ± 3 g/l). The Control Cuvette is stable over a long period (many years). The Control Cuvette should be kept in its box, protected from dust and dirt, and may be cleaned using the following procedure:

1. Use 70-95% ethanol or isopropanol (without additives) to dampen a fresh cotton swab.
2. Clean the filter of the control cuvette gently, but thoroughly.
3. Wipe dry with a fresh cotton swab.
4. Visually check that the mirrored area of the control cuvette is clean. If it is not clean, repeat the procedure.

Control Cuvette Check Procedure:

1. With power on, pull out the cuvette holder to the loading position. The Analyzer requires a 15 second waiting period ("SELFTEST") while the internal diagnostic check is completed.

2. When the main menu display reads "READY" or "PAT. TEST LOCKED-OUT," press the "QC TEST" button on the left side of the Analyzer touchpad.

3. Enter the "OPERATOR ID," if mandatory, and press the "Enter" or "C" (OK). The Bar Code Reader may also be used to enter this information.

4. "QUALITY CONTROL TEST" will appear at the top of the display. The first Control Type to appear beneath it will be the "CONTROL CUVETTE." Press "Enter" or "C" (OK).

5. The screen will then read, "QC CONTROL CUVETTE" and indicate the target value and the minimum and maximum values assigned to the Control Cuvette. These values should be checked with the values on the card that accompanies the Control Cuvette. If this is correct, press the "Enter" or "C" button (OK). If this is not correct, the Analyzer settings need to be updated using the following process. Otherwise, skip to *Step 7*.

6. Updating the values of the Control Cuvette require an *administrative security code*. The procedure is as follows:

   a. When the target value and minimum and maximum values for the Control Cuvette are displayed, and they require updating, press "B" (UPDATE).
   b. Enter the QC Password: "0000" (default password), then press "Enter" or "C" (OK).
   c. The target value and the minimum ("MIN") and maximum ("MAX") values will then reappear, with a flashing cursor at the target value. Enter the correct target value, then press the "Enter" or "C" (OK).
   d. Enter the correct MIN value and press the "Enter" or "C" (OK).
   e. Enter the correct MAX value and press the "Enter" or "C" (OK).
   f. Continue with the procedure of running the Control Cuvette.

7. Place the Control Cuvette into the cuvette holder and push it into the measuring position. The display now shows "MEASURING…" during the measurement process.

8. After approximately 15-25 seconds, the Analyzer displays a value for the Control Cuvette on the bottom left hand side of the screen. Note result and/or "PASS" or "FAIL" when the tone sounds. Pull out the cuvette holder to the loading position.

   Note**:** *If the optional* "DISPLAY QC MEASUREMENT?" *feature has not been selected in Setup Level 2, then only* "PASS" *or* "FAIL" *will be displayed together with the target value, but no measured value. However, if this feature has been selected, the actual measured value will be displayed together with the target value and* "PASS" *or* "FAIL".

9. If the Control Cuvette reading *FAILS*, DO NOT PROCEED WITH PATIENT TESTING! Follow your facility's protocol for QC failure or refer to Troubleshooting information in *Chapter 8*.

10. If this reading *PASSES*, pull out the cuvette holder to the loading position and enter a Comment Code if necessary (range is 1000 - 1099). The Bar Code Reader may also be used to enter this information (*see Appendix A*).

4.3 QCL, QCN, QCH, and QCO Level Tests: Liquid Quality Control Checks

***Note**: All appropriate laboratory safety guidelines should be followed and gloves should be worn at all times during testing procedure.*

Results for commercial controls which are assayed specifically for the HemoCue system should fall in the established ranges. If the results are unacceptable, follow your facility's protocol for failed QC tests prior to the performance of any patient testing. These results and the corrective action taken should be documented. Some control blood contains additives that cause the blood to be turbid (cloudy). The Analyzer corrects for turbidity in specimens and therefore might produce lower results than those expected for other hemoglobin instruments that do not have this correction feature. Therefore, controls assayed for the HemoCue Hemoglobin system are recommended. Please contact HemoCue Technical Support or your local distributor for names of recommended controls which have assayed values specific for the HemoCue system, thereby eliminating this potential problem.

PROCEDURE:

1. Following acceptance of testing of the Control Cuvette, the screen will automatically scroll to the next required QC Level test (i.e., "CONTROL LOW," "CONTROL NORMAL," "CONTROL HIGH," or "CONTROL OTHER). You can scroll to each QC Level by continuing to press "B" for change. When you reach the QC Level you wish to test, press "Enter" or "C" (OK).

   ***Note**: Though the Analyzer will permit you to scroll to and conduct any of the QC Level tests while in the* "QC TEST" *menu, remember that each mandatory QC test which has been user-set to* "ON" *in Setup Level 2 must be run and must obtain results within its specified range in order to proceed to Patient Testing.*

2. Follow the control manufacturer's procedure for handling of the controls.

3. The selected QC level will then be displayed with the lot number and the expiration date. If the lot number and expiration date displayed match the liquid control material, then skip to *Step 4.* However, if the Quality Control material has *expired*, you will not be allowed to continue testing until this is corrected. Updating the QC Lot # and values of the quality control require *an administrative security code*. The procedure is as follows:

   a. If using a Bar Code Reader (BCR), swipe the BCR over the control's lot number /expiration date bar code (if available).
   b. When the liquid control's lot number and expiration date are displayed, press "B" (UPDATE).
   c. Enter the "QC PASSWORD," "0000" (default password), then press "Enter" or "C" (OK).
   d. Enter the correct "QC LOT" # at the flashing cursor, the press "Enter" or "C" (OK). If a bar code reader is used for data entry, the bar coded lot number will be shown.

e. Enter the correct expiration date at the flashing cursing and then press "Enter" or "C" (OK). (***Note***: *You will not be allowed to enter an outdated expiration date)*. If a bar code reader is used for data entry, the bar coded expiration date will be shown.
f. The target value and the minimum ("MIN") and maximum ("MAX") values will then reappear, with a flashing cursor at the target value. Enter the correct target value, then press "Enter" or "C." If a bar code reader is used for data entry, the bar coded values will be shown.
g. Enter the correct MIN value and press "Enter" or "C" (OK). Enter the correct MAX value and press "Enter" or "C."
h. Continue with the procedure of running the Liquid control.

4. If the QC level, lot number and expiration date are correct, press the "Enter" or "C" button (OK).

5. The screen will then display the target, minimum (MIN) and maximum (MAX) values for the control. If these are correct, press "Enter" or "C."

6. Verify the displayed cuvette batch information against the cuvette vial. If the "BATCH" number and "EXP. DATE" are correct, press "Enter" or "C" (OK). If they are incorrect, press "B" (UPDATE). Enter the "CUVETTE BATCH PASSWORD" if required (default is "0000"), and then press "Enter" or "C" (OK). Enter the corrected information and press "Enter" or "C" (OK). ***Note****: If a bar code reader is used for data entry, the bar coded values will be shown and if an update is not needed go straight to 7.*

7. Follow the manufacturer's directions for using the control material.

8. Properly fill the microcuvette with the appropriate control material for the QC level being tested, place it in the cuvette holder, and gently insert the cuvette holder into the Analyzer. When the tone sounds, the measured value will appear on the lower left hand side of the screen under the target value and the word "PASS" or "FAIL" will appear on the lower right hand side of the screen. If the "DISPLAY QC MEASUREMENT?" option has not been chosen in Setup Level 2, then only "PASS" or "FAIL" and the target value will be displayed.

9. If this quality control reading *FAILS* (and if this level has been set as mandatory), you will not be able to proceed with patient testing. Follow your facility's protocol for failed QC testing and/or refer to the Troubleshooting Guide in *Chapter 8.*

10. Pull out the cuvette holder to the loading position and enter a Comment Code if necessary (range is 1000 - 1099). The Bar Code Reader may also be used to enter this information (*see Appendix A*).

11. Repeat the above process until all the required QC levels have been passed. When all required QC levels have been successfully tested, "READY" will be displayed.

12. Patient Testing is now enabled for the remainder of the shift period specified in Setup Level 2.

4.4 Linearity Testing

Linearity is a process that specifies a correlation between the system output and the analyte concentration. Linearity measurement demonstrates the ability of the analytical process to provide a measurement proportional to the analyte being measured over a defined range of concentrations. In order for a test of linearity to be valid, one must use an adequate number of concentrations of analyte and perform sufficient replicates. The reportable range is the range of values that a laboratory establishes as providing accurate and precise laboratory results of the method system. The reportable range is established by demonstrating linearity of results of the method system.

Note: *When performing linearity testing, it is recommended to perform all levels and duplicate testing in one session. The following procedure will take you through each level of the Linearity function. There is a maximum of 5 linearity levels. Each level can be repeated as many times as you want. If for some reason it is necessary to exit the linearity function prior to completing all desired levels, it will be necessary to begin again at Level 1 with at least one test per level. The HemoCue Communication Software provides statistical analyses of the Linearity testing. See the Software User's Guide for directions.*

1. Scroll to the QC Level "TYPE: LINEARITY" by continuing to press "B" for change. When you reach "LINEARITY," press "Enter" or "C" (OK).

2. The display screen will show "QC LINEARITY 1 TEST," the cuvette batch number, and expiration date. (***Note***: *It will only show the Cuvette Batch information if Cuvette Batch has been previously enabled in Setup Level 2)*. If displayed, verify the displayed "CUV. BATCH" information against the cuvette vial. If the "CUV. BATCH" number and "EXP. DATE" are correct, press "Enter" or "C" (OK). If they are incorrect, press "B" (UPDATE). Enter the "CUVETTE BATCH PASSWORD," if required ("0000" is the default) and then press "Enter" or "C" (OK). Enter the corrected information and press "Enter" or "C" (OK). You can also use the BCR to verify/update cuvette information.

3. Enter the Linearity "LOT NO." The number of digits allowed for the Lot No. is controlled by the maximum number of digits set for the Patient ID in Setup Level 2. Press "Enter" or "C" (OK). The BCR may also be used to enter this information

4. Follow the manufacturer's directions for using the Linearity material.

5. Properly fill the microcuvette with the linearity control material, place it in the cuvette holder, and gently insert the holder into the Analyzer. Note the displayed result. The result will be displayed until the cuvette holder is pulled out again.

6. Enter a Comment Code, if necessary (range is 1000 - 1099). The Bar Code Reader may also be used to enter this information (*see Appendix A*).

7. To repeat Linearity Level 1 test, select "C" (OK). To go on to the next Linearity Level test, press "B" (NEXT).

8. Follow steps 3 through 7 with each linearity level and desired number of repeat tests until all levels have been tested.

4.5 Proficiency Testing

Proficiency testing services can be subscribed to from several different companies which have been approved by regulatory agencies. Specimens with unknown values are sent from the external company. These samples are simulated patient samples and should be treated as such. Personnel who routinely test patient samples are to test them the same way they test real patient samples. The proficiency testing program should cover the appropriate tests and methodology and involve a large enough peer group to allow legitimate comparisons and reporting mechanisms to the customers and accrediting agencies. Testing agencies usually report results as acceptable or unacceptable and analyze them statistically in terms of standard deviation, standard deviation index, and percent difference from the mean between results reported by participants and referee laboratories.

1. Scroll to the QC Level "TYPE: PROFICIENCY" by continuing to press "B" for change. When you reach "PROFICIENCY," press "Enter" or "C" (OK).

2. Verify the displayed cuvette "BATCH" information against the cuvette vial. If the "BATCH" number and "EXP. DATE" are correct, press "Enter" or "C" (OK). If they are incorrect, press "B" (UPDATE). Enter the "CUVETTE BATCH PASSWORD" and then press "Enter" or "C" (OK). Enter the corrected information and press "Enter" or "C" (OK). You can also use the BCR to update/verify cuvette information.

3. Enter the "SPECIMEN ID" number. The number of digits allowed for the ID Number is controlled by the maximum number of digits set for the "PATIENT ID" in Setup Level 2. Press "Enter" or "C" (OK).

4. Fill the microcuvette with the proficiency control material, place it in the cuvette holder, and gently insert the holder into the Analyzer. The result will be displayed until the cuvette holder is pulled out again.

5. Enter a Comment Code, if necessary (range is 1000 - 1099). The Bar Code Reader may also be used to enter this information (*see Appendix A*).

4.6 Replacement Control Cuvette

If the Control Cuvette is lost or damaged, a new one can be ordered from your supplier. Please contact *HemoCue Technical Support or your local distributor* for more information.

This chapter will guide you through the procedure of obtaining a sample.

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***Note*:** *All appropriate laboratory safety guidelines should be followed and gloves should be worn at all times during specimen collection and testing procedures.*

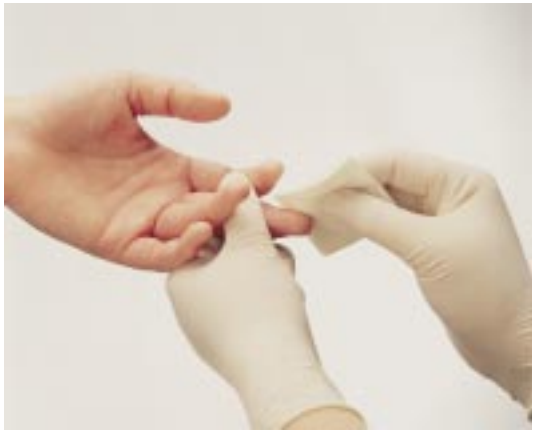
5.1. Obtaining a sample

Capillary, venous or arterial blood may be used.

5.1.1. Capillary Sampling

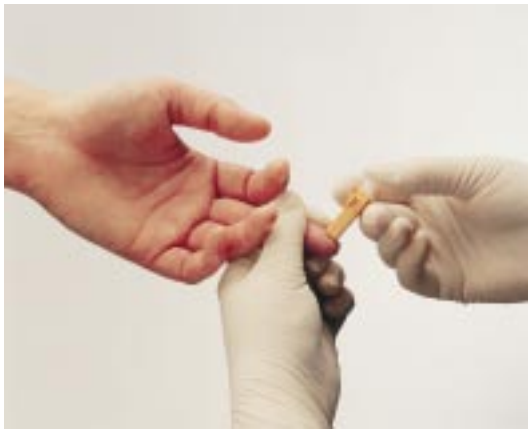
A tecchnique for capillary fingerstick is described below:

1. Make sure that the patient sits comfortably. The hand should be warm and relaxed. It is a good idea to heat cold hands in warm water before sampling. This increases the blood circulation. The patient's fingers should be straight, but not tense, to avoid stasis.



2. For best results, use the middle finger or the ring finger for sampling. Avoid fingers with rings for sampling. Clean the puncture site with disinfectant and allow it to dry. Use of safety lancets (e.g., HemoCue Safety Lancets) is suggested for safe and efficient skin puncture.

3. Using your thumb, lightly press the finger from the top of the knuckle to the tip. This stimulates the blood flow towards the sampling point.



4. With the thumb's gentle pressure at the tip of the finger, prick at the side of the tip. Not only is the blood flow at its best at this point, it also causes the least pain.

5. Wipe away the first two or three drops of blood with a dry, absorbent pad. This stimulates the blood flow. If necessary, apply light pressure again, until another drop of blood appears. Avoid "milking."

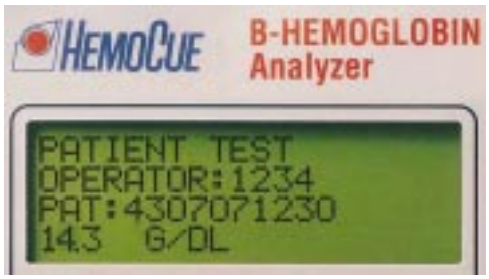
6. Make sure that the drop of blood is big enough to fill the cuvette completely. Introduce the cuvette tip into the middle of the drop.

7. Fill the cuvette in one continuous process. It should never be topped off after the first filling.

8. Wipe off the excess blood on the outside of the cuvette tip. Make sure that no blood is drawn out of the cuvette in this process. The filled cuvette should be inspected for air bubbles. Small air bubbles around the edge do not influence the result.

9. Place the filled cuvette into the cuvette holder immediately (at the latest 10 min. after it has been filled) and gently push it into the Analyzer's measuring position. See *Chapter 6* for details on Patient Testing.

   After approximately 30 to 50 seconds, the result is displayed.



10. Example of an Analyzer display with a Patient Test result.

Note: *If a second sample is to be taken from the same fingerstick, it is important that this should be done immediately after the first sample has been taken. Wipe away the remains of the first drop of blood and take a second sample from a new drop of blood.*

5.1.2 Venous or Arterial Blood from Vacuum Tubes

If collecting blood in tubes, use EDTA (ethylene diamine tetraacetic acid), heparin or heparin/fluoride as anticoagulants, preferably in solid form to avoid dilutional effects. Samples of blood collected with the recommended anticoagulants must be used within 24 hours. All samples must be allowed to come to room temperature before use and should be mixed for at least 10 minutes prior to use.

1. Obtain a specimen according to established procedure. Fresh, well-mixed, anticoagulated blood should be used.

2. Wearing gloves, point the tube of blood away from yourself (and any other persons) and *carefully* remove the cap from the tube. Tip the tube and place the cuvette tip into the surface of the blood so that the cuvette fills in one continuous motion. If the tube may need to be used for other tests, place a drop of blood onto a hydrophobic surface (for example, a plastic film) and sample the blood from that surface.

3. Follow the procedure in *Chapter 6* for performing the patient test.

5.1.3 Venous or Arterial Blood from Syringes

***Note*:** *It is very important to test the sample immediately to avoid potentially erroneous results due to coagulation or separation of the specimen.*

1. Pull back the plunger slightly and mix the blood by inverting the syringe 8-10 times.

2. While holding gauze over the end of the syringe, slowly push the plunger until a few drops of blood have been expelled. This will prime the syringe by removing any air bubbles in the tip.

3. Slowly push the plunger until a drop of blood forms at the tip. Place a drop of blood onto a hydrophobic surface. Do not fill the cuvette by pushing the syringe plunger. Introduce the cuvette tip into the middle of the drop such that the cuvette fills in one continuous motion. Wipe off the excess blood on the outside of the cuvette.

4. Follow the procedure in *Chapter 6* for performing the patient test.

This chapter will guide you through the procedure for conducting patient measurements.

6.1 Procedure for Performing a Patient Test

1. Pull out the cuvette holder into the loading position.

2. Wait for the message, "READY" to be displayed (If "PAT. TEST LOCKED-OUT" is displayed, then mandatory Quality Control tests will need to be run first. Refer to Chapter 4 for running quality control tests).

3. Press the "Patient Test" button on the Analyzer.

4. Enter "OPERATOR ID" (if mandatory) manually or use the Bar Code Reader. Then, press "Enter" or "C" (OK).

5. Enter "PATIENT ID" (if mandatory) manually or use the Bar Code Reader. Then, press "Enter" or "C" (OK).

6. If required, verify the "CUV. BATCH" and "EXP. DATE," then press "Enter" or "C" (OK). The Bar Code Reader may also be used to enter this information.

7. Take a microcuvette out of the vial. Hold the cuvette by the winged end. Reseal the vial immediately.

8. Fill the cuvette with capillary, venous, or arterial blood (see *Chapter 5*).

9. Place the filled cuvette into the Analyzer's holder and push it into the measuring position at the latest *10 minutes* after sampling. The result will be displayed in 30 to 50 seconds and remain on the screen until the cuvette holder is pulled out.

10. When the tone sounds, note the result and if it is "CRITICAL". If the value was "CRITICAL" press "C" to continue.

11. Enter a Comment Code, if enabled and desired and press "C" (OK) or Enter to continue. The Bar Code Reader may also be used to enter this information (*see Appendix A*).

6.2 Performing a STAT Test

In case of emergency the STAT (Short Turn Around Time) function will enable you to run a sample even if the Patient ID is mandatory, but not available, or if the display shows "PAT. TEST LOCKED OUT". The Patient ID can be entered after the sample has been measured.

***Note*:** *A* "STAT" *test can only be performed if the* "STAT" *function has been previously enabled in Setup Level 2.*

1. With power on, pull out cuvette holder to loading position. Wait for "READY" or "PAT. TEST LOCKED-OUT" on the display.

2. Press the "STAT" button on the Analyzer touchpad.

3. Enter "OPERATOR ID" (if mandatory) manually or use Bar Code Reader. Then, press "Enter" or "C" (OK).

4. If required, verify the "CUV. BATCH" and "EXP. DATE," then press "Enter" or "C" (OK). The Bar Code Reader may also be used to enter this information.

5. Properly fill and gently insert a cuvette. When the tone sounds, note the result and if it is "CRITICAL". If the value was "CRITICAL" press "C" to continue.

6. Enter "PATIENT ID" (if mandatory) manually or use the Bar Code Reader. Then, press "Enter" or "C" (OK).

7. Pull out the cuvette holder and enter a Comment Code if enabled and press "Enter" or "C" (OK). The Bar Code Reader may also be used to enter this information (*see Appendix A*).

This chapter will explain how the Review & List functions can be used to review and print out the information stored in the Analyzer's memory. The buttons with white lettering on the left side of the touchpad are used.

7.1 Reviewing and Listing Data

The Analyzer's memory appears as a list with stored records, but with a small observation window that shows only one record at a time on the display.

1. **REVIEW & LIST**: When the "Review & List" button is pressed, the last record stored is displayed. With the "Prev" and "Next" buttons, you can step back and forth in the list of stored results. The results are stored in *chronological order.*

2. **REVIEW MENU**: After pressing the "Review and List" button, you will be able to select the "Review Menu" button (if you press the "Review Menu" button first, you will hear an error tone). The "Review Menu" function allows you to select specific types of records you would like to review and/or print out ("PRINT"). After pressing "Review Menu," you may choose "EXIT," "PRINT," or "SELECT."

With "SELECT," you can select certain categories of records for display:

- "ALL TESTS"
- "PATIENT TESTS"
- "STAT TESTS"
- "CONTROL CUVETTE TEST"
- "CONTROL LOW TESTS"
- "CONTROL NORMAL TESTS"
- "CONTROL HIGH TESTS"
- "CONTROL OTHER TESTS"
- "LINEARITY TESTS"
- "PROFICIENCY TESTS"
- "ERROR TESTS" (i.e., lists any errors encountered during testing)
- "MAINTENANCE RECORDS"
- "SET/MOD RECORDS" (lists entries into password-protected setup levels or updates to QC or Cuvette Batch information)

After choosing one of these categories, you will be asked if you would like to further narrow the record selection to a specific "OPERATOR," PATIENT ("PAT"), "LOT," "ERROR CODE," or "MAINTENANCE CODE" (depending on the type of record category selected) and to specify a particular time frame (i.e., from "MM/DD/YY" to "MM/DD/YY"). Only those records matching the selected conditions are then displayed. If you don't want to specify a particular Operator, Patient, time frame, etc., just press "OK" to move to the next choice.

***Note*:** *If the* "DISPLAY QC MEASUREMENTS?" *option has not been selected (set to No) in Setup Level 2 for the Quality Control results, then only* "PASS" *or* "FAIL" *will be displayed if those conditions have been selected for review.*

After the desired records have been selected, pressing "Review Menu" again and then "PRINT" will initiate an output of the data to PORT 1. The Analyzer will check for a valid printer or computer connection. If a valid connection is *not* detected and "ERASE WITHOUT PRINT" in Setup Level 2 has been previously set to "NO," then the Analyzer will display "CHECK PRINTER CONNECTION" and not respond to the "OK" button until a valid connection has been established. However if "ERASE WITHOUT PRINT" was previously set to "YES," then the Analyzer will output the list of records anyway (even though it is not connected to a PC or printer).

After a listing with "ALL TESTS" selected, you are asked whether to "ERASE MEMORY." To execute, you will need a specific "ERASURE PASSWORD." See *Section 3.4, Erasing the Analyzer Memory* for details.

7.2 Reviewing Memory Displays When Using the "Review and List Function"

***Note*:** *The complete data stored in a record cannot be displayed on the Analyzer's limited display. To inspect all data associated with a measurement, list the data to a printer or PC.*

The review display always has the same format, independent of the type of record displayed:

- The top line contains Type of record, Date and Time
- The second line lists the "OPERATOR"
- The third line indicates "PATIENT ID," LOT. NO.," or "CONTROL CUVETTE"
- The bottom line has the test result or Maintenance Code

The type of record displayed (first line of display) will use the following abbreviations:

- "ADJ" ADJUST (MAINTENANCE) record
- "STA" STAT record
- "PAT" PATIENT TEST record
- "QCL" QC Liquid, Low Level record
- "QCN" QC Liquid, Normal Level record
- "QCH" QC Liquid, High Level record
- "QCO" QC Other record
- "QCC" QC Control Cuvette record
- "PT" QC Proficiency test record
- "LIB" Beginning of Linearity Test
- "LI1" QC Linearity Level 1 test record
- "LI2" QC Linearity Level 2 test record
- "LI3" QC Linearity Level 3 test record
- "LI4" QC Linearity Level 4 test record
- "LI5" QC Linearity Level 5 test record
- "MCB" Update (modify) Cuvette Batch
- "MQC" Update (modify) QC Control Cuvette values
- "MQL" Update (modify) QC Low Level expiration date/values
- "MQN" Update (modify) QC Normal Level expiration date/values
- "MQH" Update (modify) QC High Level expiration date/values
- "MQO" Update (modify) QC Other Level expiration date/values
- "ABORTED" Any measurement aborted for record types PAT, STA, QCL, QCN, QCH, QCC, QCO, PT, or LI1-5. Reported to PC with error code 990
- "SET" Stored entry into password-protected setup level
- "ERR" The stored record contains an error code
- "OVERRANGE" Any measurement over the measuring range for record types PAT, STA, QCL, QCN, QCH, QCC, QCO, PT, or LI1-5. Reported to PC with error code 999
- "BAD" The stored record contains erroneous data.

This chapter will discuss error codes and other information messages which inform the user of device conditions which might not be readily apparent.

Whenever the instrument detects an error or malfunction in the hardware or measurement system, an *error* or *information messsage* is displayed. Many errors have an associated *error code*, which is stored in an error record in the Analyzer's memory. *Information messages* are displayed on the screen in text to inform the operator of various device conditions. *Operation-Related errors* have no related error codes and are identified/described by their symptoms.
The *errors* can be divided into two main groups:

- Errors or malfunctions during a measurement
- Errors or malfunctions in the hardware during start-up and/or subsequent use

Table 8a - Information Messages		
Display	***Explanation***	***Action***
PLEASE, PULL OUT THE CUVETTE HOLDER	Black cuvette holder is in the measuring position or has been completely removed.	Pull cuvette holder out to first detent position or reinsert removed cuvette holder.
LOW BAT	When operating on battery power only, the battery voltage has dropped below 5.4V DC.	Replace with 5 AA or R6 batteries.
MEMORY FULL	Indicated in "READY" mode, there is no room left in the instrument memory for further testing.	Download, print or erase all tests in the instrument memory.
BUSY PORT 1	When connected to a PC, displayed when the instrument is communicating with the computer.	No action required. ***Note*** *- Communication may be interrupted by pressing the "*Escape*" button.*
BAD RECORD	Data storage error. Seen in Review and List.	Analyzer needs service. Call Technical Support or your local distributor.
RUN QCC	Instrument QCC has not been performed in the scheduled shift.	Run instrument QCC. Only passed tests unlock Analyzer.
RUN QCL	Instrument QCL has not been performed in the scheduled shift.	Run instrument QCL. Only passed tests unlock Analyzer.
RUN QCN	Instrument QCN has not been performed in the scheduled shift.	Run instrument QCN. Only passed tests unlock Analyzer.
RUN QCH	Instrument QCH has not been performed in the scheduled shift.	Run instrument QCH. Only passed tests unlock Analyzer.
RUN QCO	Instrument QCO has not been performed in the scheduled shift.	Run instrument QCO. Only passed tests unlock Analyzer.
RUN ALL QC TESTS	Instrument QC tests have not been performed in the scheduled shift.	Run all instrument QC tests. Only passed tests unlock Analyzer.

Table 8b - Error Messages (Displayed during measurements)			
Code	***Display***	***Explanation***	***Action***
900	ENDPOINT NOT FOUND	No stable endpoint found within the time range. 1. The cuvette is incorrect. 2. Malfunctioning optronic unit.	1a. Check expiration date for cuvette. 1b. Remeasure sample using new cuvette. 2. Analyzer needs service. Call Technical Support or local distributor.
901	LOW INTENSITY	Light intensity for the compensating diode is too low. 1. The optronic unit is dirty. 2. Malfunctioning optronic unit.	1. Clean optronic unit. 2. Analyzer needs service. Call Technical Support or local distributor.
902	LOW INTENSITY	Light intensity for the measuring diode is too low. 1. The optronic unit is dirty. 2. Malfunctioning optronic unit.	1. Clean optronic unit. 2. Analyzer needs service. Call Technical Support or local distributor.
903	DARK LEVEL	Dark voltage is too high. 1. Malfunctioning optronic unit. 2. Main power disturbances.	1. Analyzer needs service. Call Technical Support or local distributor. 2. Plug Analyzer into a different wall socket.
905	HIGH INTENSITY	Light intensity on either of the diodes is too high. Malfunctioning optronic unit.	Analyzer needs service. Call Technical Support or local distributor.
908	HIGH ABSORBANCE	The absorbance is too high, due to misuse of the system.	Call Technical Support or local distributor.
999	OVERRANGE	Measured value is greater than 25.6 g/dl (256 g/l or 15.9 mmol/l).	1. Check the expiration date of the cuvettes. 2. Remeasure sample with fresh cuvette.

Table 8c - Hardware-Related Errors

"**FATAL ERROR**" = further operation of Analyzer not allowed and the instrument should be shut off.

Code	*Display*	*Explanation*	*Action*
906	UNSTABLE BLANK ERROR ERROR CODE 906	Seen during normal use. READY (stable) state has not been found within 30 seconds of power on. 1. Instrument has been subjected to rapid temperature change. 2. Analyzer electronics are malfunctioning.	1. Remove power from instrument and allow to stabilize to ambient temperature. Return power to instrument. 2. Analyzer needs service. Call Technical Support or local distributor.
910	HARDWARE ERROR MEMORY R/W FAILED ERROR CODE 910	Seen during all phases of use, and is a fatal error. A read or write operation to the EEPROM did not succeed. EEPROM memory malfunctioning.	1. Cycle power off and on and retry testing. 2. If problem repeats frequently, call Technical Support or local distributor.
911	HARDWARE ERROR MEMORY SIZE ERROR CODE 911	Seen during start up and is a fatal error. The Analyzer cannot detect a valid EEPROM memory configuration.	1. Cycle power off and on and retry testing. 2. If problem repeats frequently, call Technical Support or local distributor.
912	HARDWARE ERROR MEMORY SIZE ERROR CODE 912	Seen during start up. Total available EEPROM memory size has changed since last restart. *The Database will be erased!*	Analyzer needs service. Call Technical Support or local distributor.
913	HARDWARE ERROR MEMORY TEST ERROR CODE 913	Seen during start up and is a fatal error. Self test of RAM memory failed. Analyzer electronics malfunctioning.	Analyzer needs service. Call Technical Support or local distributor.
914	HARDWARE ERROR LED ADJUSTMENT ERROR CODE 914	Seen at start up. During start up, the LED measuring currents could not be successfully adjusted. Memory may be read, but measurement system will not function. 1. Dirty optronic unit. 2.LED on measuring wavelength malfunctioning. 3. Analyzer electronics malfunctioning.	1. Clean optronic unit with HemoCue Cleaner. 2. Analyzer needs service. Call Technical Support or local distributor. 3. Analyzer needs service. Call Technical Support or local distributor.

Table 8c - Hardware-Related Errors "**FATAL ERROR**" = further operation of Analyzer not allowed and the instrument should be shut off.			
Code	***Display***	***Explanation***	***Action***
915	HARDWARE ERROR LED ADJUSTMENT ERROR CODE 915	Seen at start up. During start up, the LED measuring currents could not be successfully adjusted. Memory may be read, but measurement system will not function. 1. Dirty optronic unit. 2.LED on measuring wavelength malfunctioning. 3. Analyzer electronics malfunctioning.	1. Clean optronic unit with HemoCue Cleaner. 2. Analyzer needs service. Call Technical Support or local distributor. 3. Analyzer needs service. Call Technical Support or local distributor.
920	DATA ERROR MEMORY CONTENTS ERROR CODE 920	Seen at start up. EEPROM memory inconsistent. Setup levels will be reset to defaults *and memory will be erased and reinitialized.* Analyzer electronics are malfunctioning.	Analyzer needs service. Call Technical Support or local distributor.
921	DATA ERROR MEMORY BAD ERROR CODE 921	Seen during measuring and is fatal. Testing of EEPROM configuration returned erroneous checksum. Instrument will be locked out.	1. Turn instrument off then on to reset. 2. If problem continues, call Technical Support or local distributor.
923	DATA ERROR REAL TIME CLOCK ERROR CODE 923	Seen at start up. *Date, Time and any memory will be lost.* Real Time Clock backup battery has been drained.	Back up battery needs to be replaced. Call Technical Support or local distributor.
924	DATA ERROR DATABASE CONTENTS ERROR CODE 924	Seen at start up. The database has inconsistencies and must be erased and reinitialized. RTC back up battery has been drained.	Back up battery needs to be replaced. Call Technical Support or local distributor.
925	UNCALIBRATED ERROR CODE 925	Seen at start up and is fatal error. Calibration checksum is not valid. Instrument needs calibration.	Call Technical Support for assistance.

Table 8d - Operation-Related Errors		
Symptom	***Explanation***	***Action***
Display is unreadable or gives erroneous characters.	1. Display is malfunctioning. 2. Analyzer electronics are malfunctioning.	Analyzer needs service. Call Technical Support or local distributor.
Control Cuvette gives erroneous results.	1. The control cuvette is cracked or dirty. 2. The optronic unit is dirty. 3. Wrong control cuvette for instrument. 4. The control cuvette is upside down in cuvette holder.	1a. Check if control cuvette is cracked. If cracked, replace. Call Technical Support for assistance. 1b. Clean control cuvette, see *section 4.2* of the manual. 2. Clean the optronic unit. 3. Check that the serial number of the control cuvette matches the serial number of the instrument being tested. 4. Check that control cuvette is inserted correctly. 5. If problem persists, call Technical Support or local distributor.
The display does not switch from "SELFTEST" or from "PLEASE PULL OUT CUVETTE HOLDER" to "READY".	1. The magnet in the cuvette holder may be missing. 2. The reed switch in the optronic unit is out of order.	The Analyzer needs service. Call Technical Support or local distributor.
The display shows "LOW BAT".	1. The batteries need to be replaced. 2. If on main power, the optronic unit or the circuit board is out of order.	1. Turn off the Analyzer and replace the batteries, five type R6 or AA. 2. The Analyzer needs service. Call Technical Support or local distributor.
Too high or too low results when checking liquid controls.	1. Cuvettes are damaged or too old or have been stored incorrectly. 2. Optical eye of the cuvette has been contaminated. 3. Liquid control has not been prepared properly. 4. Liquid control has been contaminated or is out of date. 5. Air bubbles present in the cuvette and/or control. 6. The optronic unit is dirty. 7. The control is not usable with the HemoCue System. 8. The calibration of the instrument has changed.	1. Check the expiration date and storage of the cuvettes. 2. Remeasure the sample with a fresh cuvette. 3. Make sure all procedures for preparing controls have been followed. 4. Check expiration date of controls. Remeasure sample using fresh controls. 5. Check cuvette for air bubbles. If present, remeasure sample with a fresh cuvette. 6. Clean optronic unit. Call Technical Support or local distributor. 7. Check control package insert for applicability to HemoCue System. 8. Measure control cuvette. If control cuvette value is out of range, instrument may need calibration. Call Technical Support or local distributor.

Table 8d - Operation-Related Errors		
Symptom	***Explanation***	***Action***
Too high or too low values on patient samples compared to those expected.	1. Cuvettes are damaged or too old or have been stored incorrectly. 2. Optical eye of the cuvette has been contaminated. 3. Air bubbles present in the cuvette. 4. The optronic unit is dirty. 5. The calibration of the instrument has changed. 6. Incorrect sampling technique.	1. Check the expiration date and storage of the cuvettes. 2. Remeasure the sample with a fresh cuvette. 3. Check cuvette for air bubbles. If present, remeasure sample with a fresh cuvette. 4. Clean optronic unit. 5. Measure control cuvette. If control cuvette value is out of range, instrument may need calibration. Call Technical Support or local distributor. 6. Review *Chapter 5* for sampling techniques and remeasure sample with fresh cuvette.

This chapter will provide detailed information, geared primarily for biomedical engineers or computer specialists, regarding how the Analyzer is configured to output data to peripheral devices such as PC's or printers and to receive data from external Bar Code Readers (BCR).

The Analyzer communicates via two RS232 ports which are located on the top side panel. Both ports have two-way communications capabilities, including hardware handshake signals. To preserve power, the ports have a shut-down feature.

PORT 1 may be used to establish a two-way communications link to a host computer (called PC from here on), or alternatively, an output-only connection to an 80-column printer. The communications parameters are set in Setup Level 1. To ease the interface of HemoCue Data Management Analyzers to Laboratory and Hospital Information Systems (LIS and HIS), a simple Application Programming Interface (API) is defined.

PORT 2 may be used for output of a single patient record to a small (label) printer (minimum 20 columns) and for receiving input from a Bar Code Reader (BCR). The communications parameters are fixed, but the printer output may be completely disabled in Setup Level 1.

9.1 Communications Parameters

The communications parameters of both serial ports are set in Setup Level 1. PORT 1 parameters are programmable and PORT 2 parameters are fixed.

Table 9a - RS 232 Communications Parameters

Parameter	**PORT 1**	**PORT 2**	
	Rx / Tx	Rx	Tx
Baud Rate	9600, 4800, 2400, 1200	1200	1200
Data Bits	8, 7	7	8
Parity	NO, ODD, EVEN	EVEN	EVEN
Stop Bits	1	1	1

**The underlined settings are the default settings of* PORT 1.

9.2 Hardware Connections

The serial ports of the Analyzer emulate the DB9 connector of a PC-AT; thus, a communications cable intended for PC-to-PC connection is also the proper connection between the Analyzer and a PC.

Table 9b – RS232 Connector Pinouts

DB 9	PORT 1		PORT 2	
Pin No	**Signal Name**	**Direction**	**Signal Name**	**Direction**
1	DCD	No Connection	DCD	No Connection
2	RxD	To HemoCue from PC	RxD	To HemoCue from BCR
3	TxD	From HemoCue to PC	TxD	From HemoCue into Printer
4	DTR	Same as RTS (pin 7)	DTR	Same as RTS (pin 7)
5	S. Ground	Ground	S. Ground	Ground
6	DSR	To HemoCue from PC	DSR	No Connection
7	RTS	From HemoCue to PC	RTS	From HemoCue to Printer
8	CTS	To HemoCue from PC	CTS	To HemoCue from Printer
9	+5V max. 20mA	Power to Peripheral Unit	+5V max. 20mA	Power to Peripheral Unit

- To preserve power, the communications chip is normally in a power down state and the DSR line (pin 6) on PORT 1 must be asserted (high) to power up the interface ports. This receiver is always active, independent of the power-down status of the interface chip.
- The RxD line (pin 2) on PORT 2 is always active and ready to receive data from the BCR, independent of the power-down status of the interface chip.
- The absolute maximum current drawn from pin 9 is 20 mA. Pin 9 of both ports may be connected in parallel to double this. Please note that this will *substantially shorten the battery life time*, if running on battery power.

9.3 PORT 1 Communications

PORT 1 may be used for communication with two different types of devices: Personal Computers and Printers. The characteristics of the communications are dependent on how the PC communications are configured in Setup Level 1 and in the connected device, or, to be more precise, whichever device is the initiating party of a data transfer, the Analyzer or a PC.

9.3.1 PORT 1-to-PC Communications

For Analyzer to PC communications, the Analyzer Communication Software program must first be installed on the PC.

With a PC connection, a two-way communications link is established, thus making block transfers with an error-detecting checksum and software handshaking viable.

All communications between the HemoCue Data Management Analyzer and a PC are controlled from the PC. The measurement data is stored in non-volatile memory and is transferred to the PC on request (READ or READ_ALL). However, there are two settings of the PC communications - On-line and Batch.

- **On-Line Communications:** Used with a permanent connection to the host computer. Each record is erased from the instrument database immediately after a successful transfer to the PC, in response to a READ_ALL command from the PC.

- **Batch Communications:** When the instrument is used as a stand-alone, an explicit command, ERASE_DB, is required from the PC to erase (see *Section 3.4*). In Batch-mode, READ_ALL/READ does not affect the internal memory at all.

9.3.2 Application Programming Interface

The API consists of a set of command messages, sent by the PC, and the response from the Analyzer is a block transmission or simple ACK, NAK, or BUSY strings (please note that ACK and NAK are 3-character strings, not the control characters).

Table 9c - Application Programming Interface

Message	Description	Response
READ	From PC: Read Next Record(s) not previously read, from database	Analyzer transmit measurement record block
READ_ALL	From PC: Read All Records in database, even if previously read	Analyzer transmit measurement record block
ERASE_DB	From PC: Erase all data in instrument Database (memory)	Analyzer transmit ACK, when memory erased
PM_STAT_GET	From PC: Read Status of instrument	Analyzer transmit Status block
CFG_GET	From PC: Read Configuration of instrument	Analyzer transmit Configuration block
SETUP0_GET	From PC: Upload Instrument Setup	Analyzer transmit Setup block 0
SETUP1_GET	From PC: Upload Instrument Setup	Analyzer transmit Setup block 1
SETUP2_GET	From PC: Upload Instrument Setup	Analyzer transmit Setup block 2
SETUP0_SET	From PC: Download Instrument Setup, Block 0	Analyzer transmit ACK/NAK, at end of each block
SETUP1_SET	From PC: Download Instrument Setup, Block 1	Analyzer transmit ACK/NAK, at end of each block
SETUP2_SET	From PC: Download Instrument Setup, Block 2	Analyzer transmit ACK/NAK, at end of each block
BUSY	From Analyzer: When not in "READY" state	None
ACK	From PC and Analyzer: After a successful block receive	None

9.3.3 Read Database Sequence

- The transmission is requested by the PC via a 'READ_ALL' or 'READ' command.
- The instrument transmits the database record(s) consecutively, in chronological order.
- Each record constitutes a block as described below.
- The PC calculates the checksum of each received block and compares it with the checksum contained in the block.
- If the checksums match, an 'ACK' is issued and, if not, a 'NAK' is issued by the PC.
- The instrument analyzes the response of the PC and if it is 'ACK,' it continues with the next record. If the response is 'NAK', the same block is sent in its entirety once more.
- The end of a block transmission is signaled by a null block (no data characters) by the instrument.
- Detailed structure of all available communication blocks can be read in "Data Management Analyzer Application Programming Interface." This document is provided by HemoCue upon request.

9.3.4 General Communications Block Structure

Transfer of Measurement Records, Configuration and Calibration parameters are executed as block transmissions. An error-checking *checksum* is appended to the data in each block. Thus, the integrity of the transferred data may be validated by the receiver and either acknowledged or not acknowledged depending on the outcome. The block has a variable length depending on the number of data characters in the block. The maximum size of the block is sufficient to contain a single record. However, block transfers are not limited to measurement data alone, but the structure of the record is always the same:

1. STX	Start of transmission (STX = 02 hex).
2. NCh	Number of characters, from STX to ETX and including these. The format transmitted is 3 decimal characters.
3. Data characters	Variable length (one record). Data fields are separated (framed) by ; (semicolon).
4. ETX	End of transmission (ETX = 03 hex).
5. CSum	8 bit checksum, from STX to ETX and including these. The format transmitted is 3 decimal characters.
6. CR	Carriage Return (CR=0D hex).
7. LF	Line Feed (LF=0A hex).

- The checksum is calculated as the 8-bit sum of all bytes (ASCII character code values) in the transmission block, from STX to ETX with these included, with no consideration to the carry.
- A null block (0 data characters) marks the end of a, possibly multi block, dump.
- The maximum-specified length of a block (NCh) is 127 characters. Hence, with 5 trailing characters, the total length will be 127 + 5 = 132 characters.

9.3.5 Structure of Measurement Record

1.	STX	Start of transmission (02H).
2.	NChar;	Number of characters, from STX to ETX and including these.
3.	S.No;	Serial number of the instrument.
4.	CuvBatch;	Cuvette Batch Number.
5.	CuvExpDate;	Cuvette Expiration Date.
6.	Date;	Date of sample.
7.	Time;	Time of sample.
8.	OpID;	Operator id.
9.	PatID;	Patient id or Control Lot Number.
10.	Type;	Type of measurement (PAT, QCC, QCL...etc).
11.	Val;	Value of sample.
12.	Units;	Units of measurements.
13.	P/F;	Pass/Fail marking for QC or Critical/[blank] for PAT & STAT.
14.	QC_Min;	Minimum value of QC range or Critical min.
15.	QC_Max;	Maximum value of QC range or Critical max.
16.	QCExpDate;	Liquid Control Expiration Date.
17.	Comt;	Comment code.
18.	ETX	End of transmission (03H).
19.	CSum	8 bit checksum, from STX to ETX and including these.
20.	CR	Carriage return
21.	LF	Line feed

9.3.6 Serial Printer on PORT 1

An 80-column printer with RS232 serial interface may be connected to PORT 1 as an alternative to the PC connection. Printouts of the memory contents may be issued from the touchpad of the Analyzer.

With a Printer connected to PORT 1, a send-only communications link is established, thus making block transfers with error detecting checksums and software handshaking impossible. However, the connection of an output device is checked by the hardware handshake line, CTS (pin 8), which must be asserted (high) to enable printing. This check may be disabled in Setup Level 2 (to ease demonstrations).

1. Listings to Printer on PORT 1

    - The listing is requested by the operator, by a "PRINT" command in "Review & List."
    - The listings are in accordance with the current selections in the "Review & List" function of the Analyzer.
    - The Analyzer transmits the selected records consecutively, in chronological order.
    - In order to fit the listing to an 80-column printer, it is formatted with each record occupying 1 or 2 lines, as exemplified below.
    - A heading is output at the top of each new list.
    - If Cuvette Batch parameters are set to OFF in Setup Level 2, then these two fields are blank in the list.
    - The first character on each line is indented to column 5, to allow paper with punched holes.
    - Space characters are used to separate the fields within each record.
    - End of line is marked by appending the characters 'CR' and 'LF.'
    - The instrument analyzes the response of the Printer through the hardware handshake signal, thus letting the Printer control the pace of the listing.

9.3.7 PORT 1, Printer List Format

```
  COLUMN:
00000000011111111112222222222333333333344444444455555555556666666666777777777 8
12345678901234567890123456789012345678901234567890123456789012345678901234567890
```

```
HEMOCUE B-HEMOGLOBIN           03/18/00     01:27 AM
ANALYZER SER.NO:9551-701 074

DATE      TIME    OPERATOR   PATIENT/LOT     TYPE      VALUE       COMT
                  CUV.BATCH  CUV.EXP.DATE    P/F       QC.RANGE    QC.EXP

03/17/00  01:47AM 1234567890 123456789012345 PAT       11.6 g/dl   1099
                  9050014    06/01/01        CRITICAL  0.0-12.0

03/17/00  01:48AM 1234567890 123456789012345 STA       14.3 g/dl   1098
                  9050014    06/01/01                  0.0-12.0

03/17/00  01:49AM 1234567890 123456789012345 PAT       13.6 g/dl   1097
                  9050014    06/01/01                  0.0-12.0

03/17/00  01:49AM 1234567890 123456789012345 STA       15.7 g/dl   1096
                  9050014    06/01/01                  0.0-12.0

03/17/00  01:51AM 1234567890                 QCC       12.7 g/dl   1095
                                             PASS      12.4-13.0

03/17/00  01:52AM 1234567890 1001            QCL       7.0 g/dl    1094
                  9050014    06/01/01        FAIL      7.6-8.4     06/30/00

03/17/00  01:53AM 1234567890 2001            QCN       12.0 g/dl   1093
                  9050014    06/01/01        PASS      11.4-12.6   06/30/00

03/17/00  01:54AM 1234567890 3001            QCH       16.0 g/dl   1092
                  9050014    06/01/01        PASS      15.2-16.8   06/30/00

03/17/00  02:04AM 1234567890                 ADJ       987         0
```

9.4 PORT 2 Communications

9.4.1 Small Serial Printer on PORT 2

A 20-column printer with RS232 serial interface may be connected to PORT 2. Each measurement record is immediately printed when the result is ready. The preferred device to connect is a small label printer. The label may be easily transferred to the patient file. This output on PORT 2 may be completely disabled in Setup Level 1.

- Immediate Printout of One Measurement Record

  1. The listing is initiated by the Analyzer at the end of a measurement.

  2. The instrument analyzes the response of the Printer through the hardware handshake signals, thus letting the Printer control the pace of the listing.

  3. A copy of a PORT 2 printout is generated by pressing "Review & List" and then "B."

  4. 'CR' and 'LF' characters are used to separate the fields within each record.

- Record Structure Samples

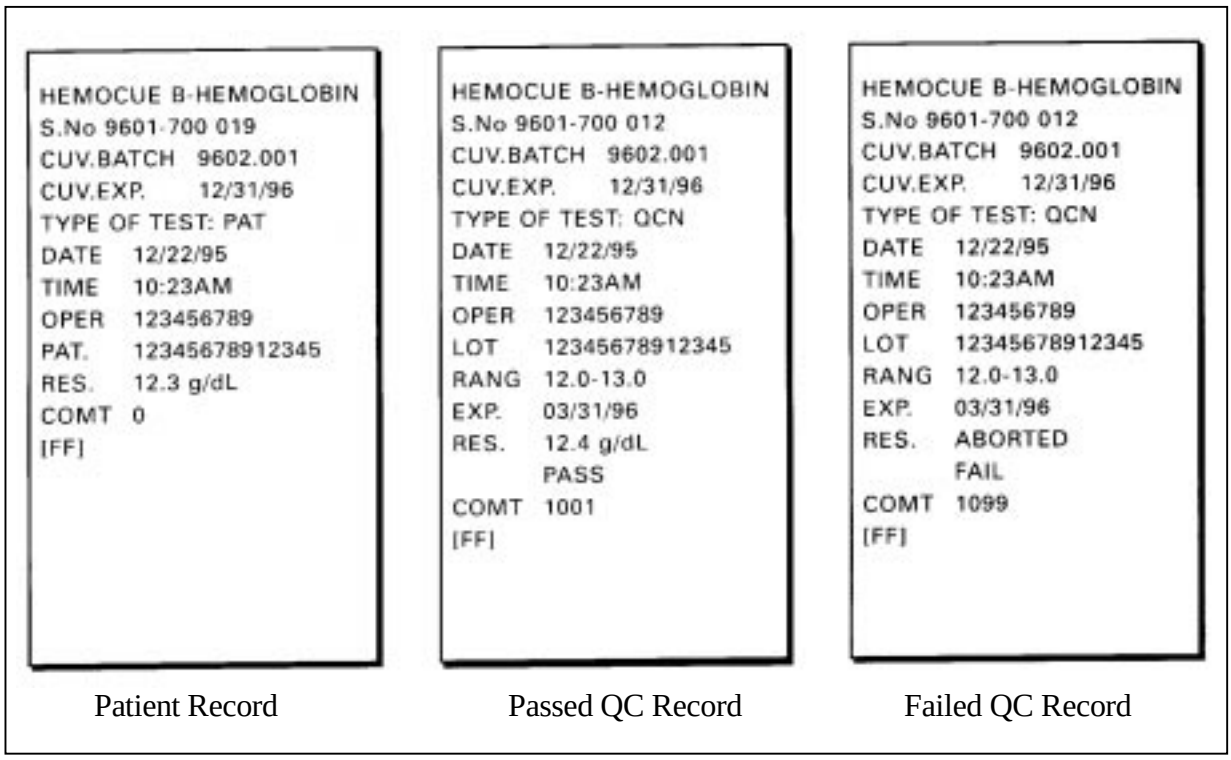


***Figure 9A**: Sample Record Print-outs*

If Cuvette Batch parameters are set to "OFF" in Setup Level 2, then the two fields in question (lines 3 and 4) are not output to the list.

9.4.2 Bar Code Reader on PORT 2

A Bar Code Reader (BCR) which uses an RS232 interface may be interfaced with the Analyzer and can be powered by the Analyzer via pin 9 of the RS232 connector. However, the current required by the reader must not exceed 20mA.

With a BCR connected to PORT 2, a receive-only communications link is established. This may be used to enter operator and patient data in a quick and reliable way, i.e., it is an alternate way for the operator to enter parameters. Data from the BCR is received through a RS232 receiver which is always on, independent of the power down status of the interface chip, thus it is always possible to receive BCR data. Contact HemoCue Technical Support or your local distributor for suggestions on compatible Bar Code Readers.

10.1 HemoCue B-Hemoglobin Analyzer - Specifications

Dimensions	16.0 x 21.0 x 9.0 cm (6.29 x 8.25 x 3.54 inches)
Weight	1 kg (2 pounds)
Power	Drawn from HemoCue AC Adapter or internal batteries. 120V AC Adapter : 120V AC (105-135), 60 Hz, Output 6V DC, 500 mA. 230V AC Adapter: 230V AC, 50 Hz, Output 6V DC, 350 mA. The Analyzer is protected through the self-protected design of the transformer. This means that, even if short-circuited, a hazardous event is remote. The Analyzer has an internal voltage regulator with a built-in current-limiting function to protect the circuits. Battery-powered: The Analyzer is equipped with a voltage monitor which will display "LOW BAT" (only when powered by batteries). Regardless of the power source, if the voltage is too low to guarantee an accurate measurement, the Analyzer will shut down and no measurement will be permitted.
Operating Temperature	15-40° C (59-104° F)
Storage Temperature	0-50° C (32-122° F)
Mode of Operation	Continuous
Protection Against Ingress of Water	Ordinary
Measurement Range	The test is linear up to 23.5 g/dl (235 g/l or 14.6 mmol/l). Values above 23.5 g/dl must be confirmed using a suitable laboratory method. Values above 25.6 g/dl (256 g/l or 15.9 mmol/l) are displayed as "OVERRANGE" ("999" on the data printout).
Calibration	The Analyzer is delivered calibrated against the hemiglobincyanide (HiCN) method, which is the international reference method for the determination of the total hemoglobin concentration in blood. If recalibration is required call HemoCue Technical Support or your local distributor.

EMC	The HemoCue Data Management Analyzer meets the requirements in the EMC directive 89/336/EEC, with amendments 92/31/EEC and 93/68/EEC.
Method	Vanzetti, G., J. Lab. and Clin. Med., 67:1, 116 (1966).
Principle	Sodium deoxycholate hemolyzes the erythrocytes and hemoglobin is released. Sodium nitrite converts hemoglobin to methemoglobin which, together with sodium azide, gives azidemethemoglobin. The absorbance is measured at two wavelengths (570 and 880 nm), in order to compensate for turbidity in the sample.

10.2 HemoCue B-Hemoglobin Microcuvettes - Specifications

Description	The microcuvette is made of polystyrene plastic and has a body cavity which uptake approximately 10 µl of blood. The cuvette cavity contains reagents deposited on its inner walls and the blood sample is drawn into the cavity by capillary action and is spontaneously mixed with the reagents. The distance between the walls of the microcuvette optical window is 0.13 mm, which permits photometric determination of hemoglobin in undiluted blood.
Reagents	Sodium deoxycholate, sodium nitrite, sodium azide, non-reactive ingredients

Storage and Stability

Microcuvettes should be stored at room temperature, 18-30° C (59-86° F), at a dry place. The vial should be kept tightly capped and cuvettes should be removed only as needed for testing, just prior to use. Do not refrigerate. Unopened vials have a shelf life of 2 years from the date of manufacture. The expiration date is printed on each vial.

Vials of cuvettes that have been opened are stable for three (3) months from the date opened, with the cap kept on tightly between use. Label each vial with the date that it was opened.

The reagents within the HemoCue Microcuvette are moisture sensitive. Replace the cap immediately after microcuvettes are removed from the package. As this test method relies on photometric measurement, care should be taken not to hold the microcuvette by the filling tip. Also take care to wipe away all types of contaminating substances from the sides of the cuvette. All unused microcuvettes must remain in their original package.

Discard the cuvette in an appropriate biohazard container. All sharps should be disposed of in a container approved for such use.

WARNING: HemoCue B-Hemoglobin Microcuvettes are for ***In Vitro Diagnostic use only***. The chemicals deposited in the cavity of the microcuvette are harmful if swallowed. Although the reagents are present in the microcuvette in extremely low quantities, consult local environmental authorities for appropriate disposal.

10.3 Expected Values

The following hemoglobin values are considered normal:

- Adult males 13.0-18.0 g/dl (130-180 g/l or 8.1-11.2 mmol/l)
- Adult Females 11.0-16.0 g/dl (110-160 g/l or 6.8-9.9 mmol/l)
- Infants, after neonatal period 10.0-14.0 g/dl (100-140 g/l or 6.2-8.7 mmol/l)

Children, two years to teenage: gradual increase to adult normals.

Due to the wide range of conditions (dietary, geographical etc) which affects normal values, it is recommended that each laboratory establish its own normal range.

10.4 Limitations of the Procedure

1. Measurement of hemoglobin should be made as soon as possible after the blood has been drawn into the cuvette. If the readings in the Analyzer are made later than 10 minutes after the blood has entered the cuvette, false results may be obtained. It should be noted that oxygenated blood which has been agitated over a long period produces oxygen pressure and viscosity at higher than normal levels. The achievement of accurate results for blood in this condition requires analysis to be undertaken immediately after the cuvette has been filled.

2. If air bubbles are seen in the optical eye of a blood-filled microcuvette, the microcuvette should be discarded and another sample taken for analysis.

3. Precaution should be taken not to hold the cuvette by the filling end. This can contaminate the optical eye. Care should be taken in wiping off excess blood from the outer surface of the optical eye.

4. Values above 23.5 g/dl (235 g/l or 14.6 mmol/l) must be confirmed using a suitable laboratory method.

5. Sulfhemoglobin is not measured with this method. Carboxyhemoglobin and turbidity due to leukocytosis or hyperlipemia do not interfere.

10.5 Maintenance

The Analyzer was designed to work for a long period of time without any direct service. No preventative maintenance is needed for the electronic parts of the Analyzer. The cuvette holder should be cleaned daily with alcohol or a mild soap solution, after having been completely removed from the Analyzer first. It can also be autoclaved. It is important that the holder is *completely dry* before being replaced in the Analyzer.

The Analyzer's cover may be cleaned, as needed, with alcohol or a mild soap solution.

To clean the optronic unit (the area inside the unit that the cuvette holder inserts into), use of the HemoCue Cleaner is recommended (follow the instructions in its package).

10.6 Entering Maintenance Records/Activities into the Analyzer

The memory of the HemoCue Data Management Analyzer may be used as a log book for manual service and maintenance activities (such as 'optronic unit cleaned'). Maintenance Records store the time and date of entry, Operator ID (if mandatory), and the service or maintenance activity (stored as a code). The Maintenance Code range is 970 - 989 and the codes are user-defined. Maintenance Records are stored as type "ADJ" (adjust) in the Analyzer's memory.

To document service or maintenance activities, follow these steps:

1. With power on, pull out the cuvette holder into the loading position.

2. Press the "Setup" button and enter your "OPERATOR ID" (if mandatory).

3. When the screen displays, "ENTER PASSWORD," select "MAINT" ("B") to *change* the selection to "ENTER MAINTENANCE RECORD?" Press "C" (OK) or "Enter."

4. When the screen displays, "ENTER MAINTENANCE CODE:," enter a user-defined code from 970 to 989. Press "C" (OK) or "Enter." ***Note***: *The Maintenance Code can also be entered via a Bar Code Reader.*

10.7 Technical Service/Repair

The Analyzer carries a 12 month guarantee from the date of receipt.

After the warranty period, service/repair is made at fixed prices. During the period of service/repair, a loaner Analyzer can be obtained from your distributor.

Contact HemoCue Technical Support or your local distributor regarding return for service or repair**.**

10.8 Bibliography

1. Stadie, W.C., J. Biol. Chem. 41, 237 (1920)

2. Drabkin, D.L. and Austin J.H., J. Biol. Chem. 98, 719 (1932)

3. Austin, J.H. and Drabkin, D.L., J. Biol. Chem. 112, 67 (1935-36)

4. Van Kampen, E.J. and Zijlstra, W.G., Clin. Chem. Acta 6, 538 (1961)

5. Vanzetti, G., Am. J. Lab. & Clin. Med. 67, 116 (1966)

6. Gradwohl´s Clinical Laboratory Methods and Diagnosis, Frankel, S., Reitman, S. And Sonnenwith, A.C., Editors, C.V. Mosby Co., St. Louis, 7th Edition, 1970 Vol, 1, p. 405

7. ICSH Standard EP 6/2: 1977, Standard EP 6/3: 1977, V. Clin. Path. 3/1 139-143 (1978)

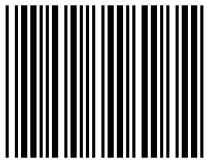
8. Makarem, A. In Clin. Chem. Principles and Technics, 2nd ed., Henry R.J., Cannon, D.C., and Winkelman, J.W., Eds., Harper and Row, Hagerstown, MD, 1974, pp. 1127-1147

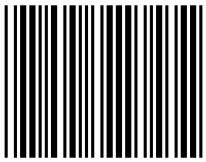
9. Wallach, J.Interpretation of Diagnostic Test, 1st ed., Little, Brown and Company, Boston, MA, 1970, pp. 6-7

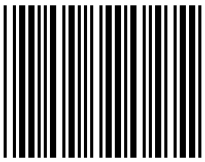
10. HemoCue Operating Manual, HemoCue AB, Ängelholm Sweden

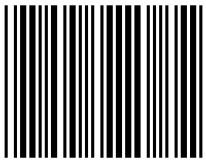
A Bar Code Reader (BCR) may be used to enter various data into the Analyzer. This includes entry of the user-definable Maintenance Codes (970-989) and Comment Codes (1000-1099). For user convenience, this Appendix provides the bar code sequences for both the Maintenance Code and Comment Code ranges.

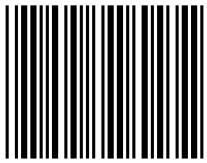
A.1 Maintenance Codes

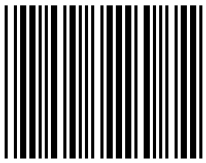

970

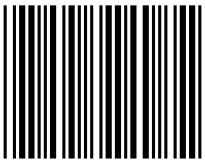

971

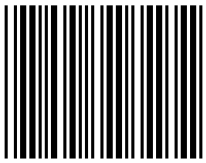

972

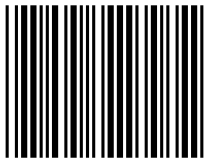

973

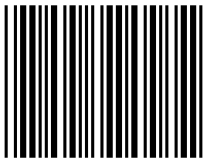

974


975


976


977


978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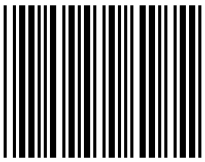
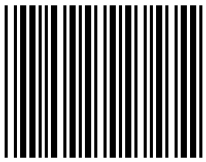

980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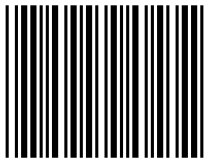
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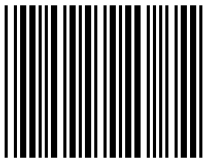
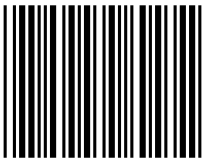

983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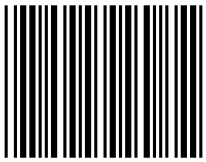
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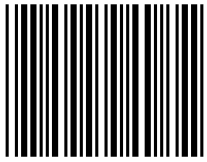
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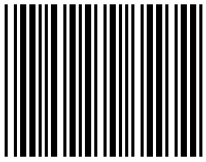
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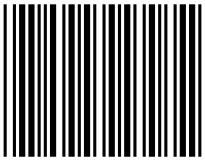
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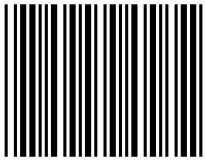
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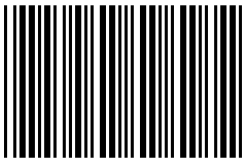
A.2 Comment Codes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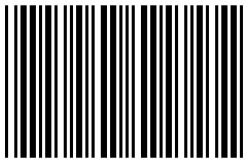
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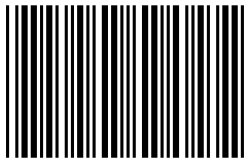
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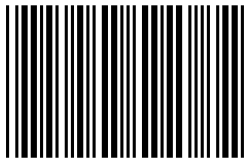
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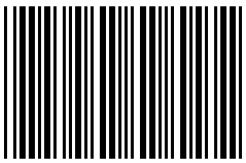
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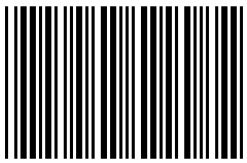
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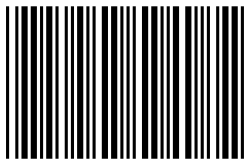
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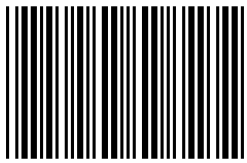
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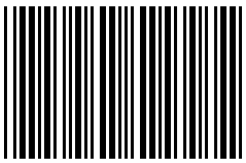
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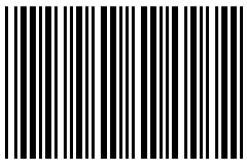
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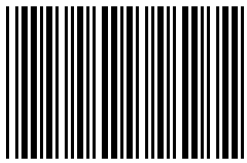
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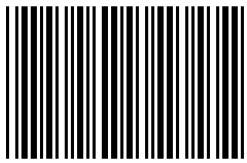
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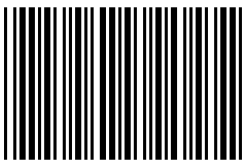
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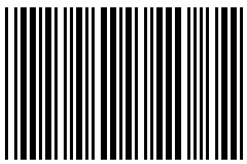
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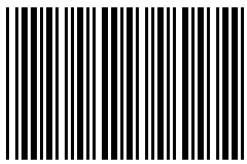
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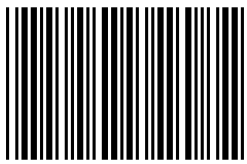
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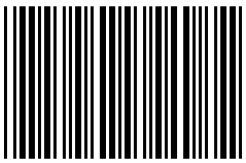
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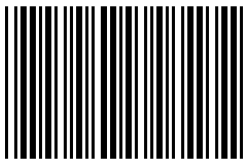
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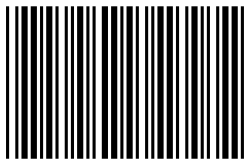
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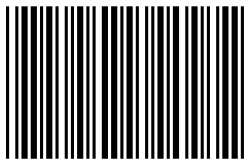
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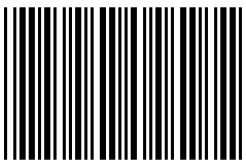
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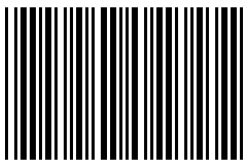
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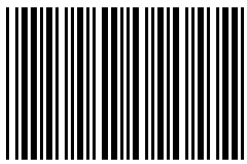
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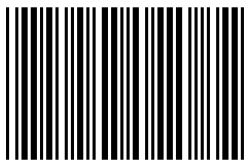
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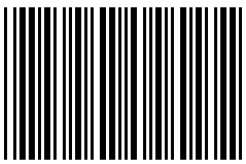
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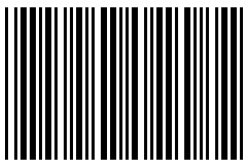
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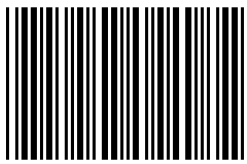
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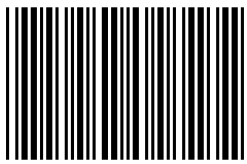
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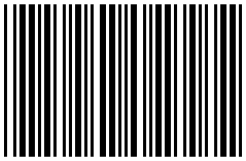
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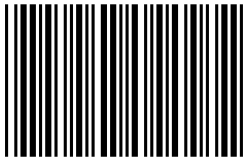
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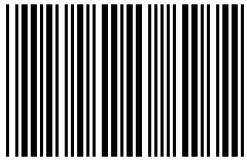
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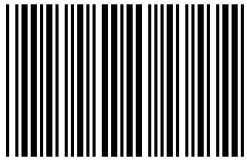
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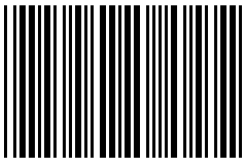
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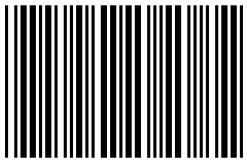
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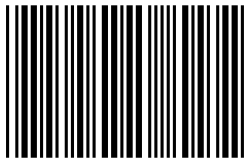
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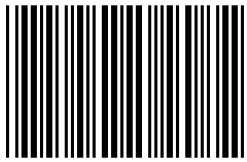
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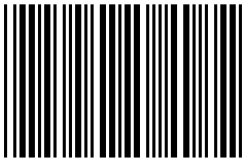
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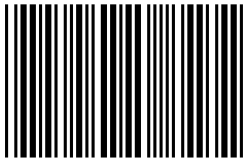
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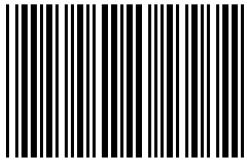
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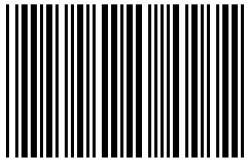
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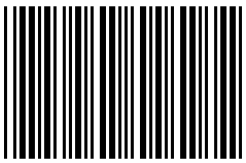
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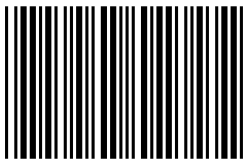
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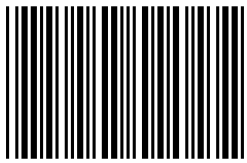
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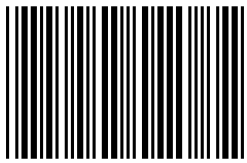
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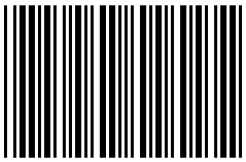
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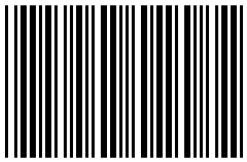
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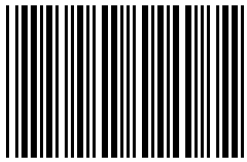
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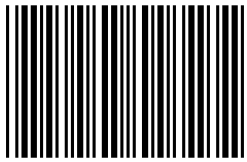
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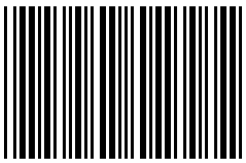
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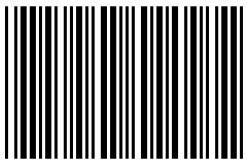
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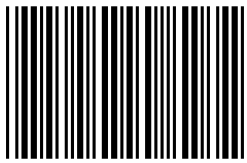
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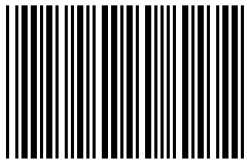
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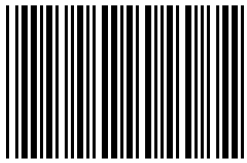
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Comment Codes - continued


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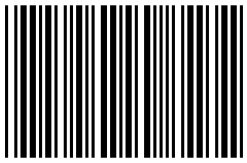
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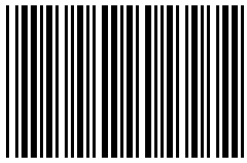
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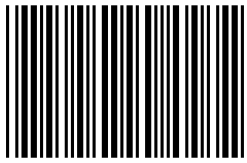
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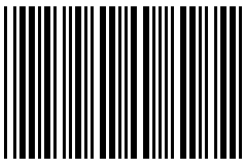
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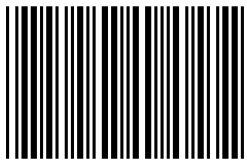
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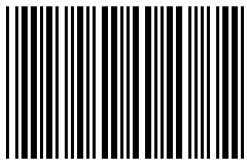
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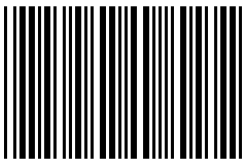
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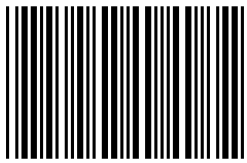
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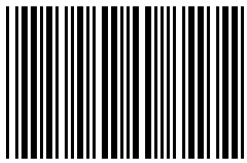
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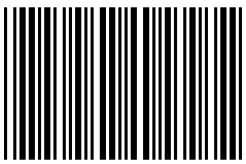
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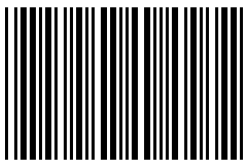
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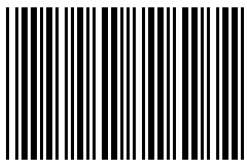
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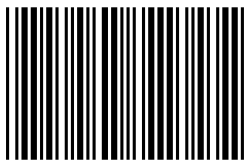
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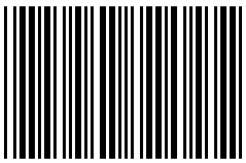
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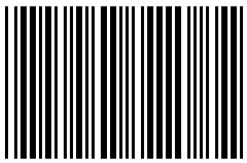
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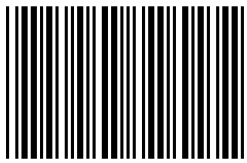
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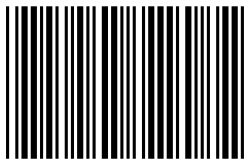
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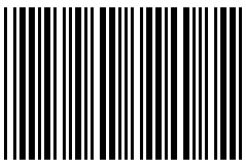
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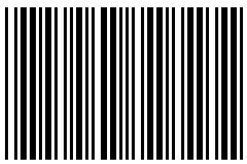
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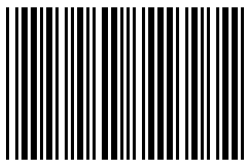
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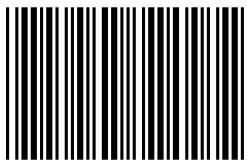
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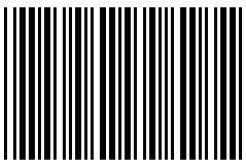
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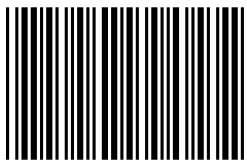
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Comment Codes - continued


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